

FEB 24 2012

510(K) SUMMARY

510(K) Number K 120301

Applicant's Name:

St. Jude Medical
MediGuide Navigation Systems
Advanced Technology Center, POB 15003, Haifa, Israel
Tel: +972-4-8137000
Fax: +972-4-8550412

Contact Person:

Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Tel: (202) 637-5794
Fax: (202) 637-5910
Mail: jonathan.kahan@hoganlovells.com

And/Or

Merav Yarmus, Ph.D.
Biomedical Strategy (2004) Ltd.
7 Jabotinsky Street.
Ramat Gan 52520, Israel
Tel: +972-3- 6123281
Fax: +972-3-6123282
Mail: merav@ebms.co.il

Date Prepared:

January, 2012

Trade Name:

MediGuide Technology

Classification Name:

Programmable diagnostic computer

Product Code:

DQK

Device Class:

II

Regulation Number:

870.1425

Panel:

Cardiovascular

Predicate Devices:

Guided Medical Positioning System II (gMPS™ II) [MediGuide Ltd.] cleared under K102905.

Intended Use / Indications for Use:

The MediGuide Technology System is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

Device Description:

The MediGuide Technology System, used in conjunction with an X-ray System, employs magnetic positioning technology to track a MediGuide enabled diagnostic or therapeutic invasive device for the 3D position relative to any X-Ray image, in real-time or previously recorded cine-loop.

The MediGuide Technology System includes two optional software packages. The Coronary package includes the Coronary application, and it supports coronary procedures. The Cardiac package includes the Cardiac Navigation application and the Cardiac Navigation with Angio Survey™ application, both support cardiac procedures.

The most fundamental capability of the MediGuide Technology is the positioning and navigation of MediGuide enabled devices. This feature enables projection of the real time position of a MediGuide sensor (and thus of the MediGuide enabled device) on real time 2D X-Ray images (live mode) or in a recorded mode (the MediGuide enabled device tip real time position is superimposed on a previously recorded cine loop or still image). The MediGuide Technology enables simultaneous tracking of up to three MediGuide enabled devices.

In addition, the MediGuide Technology provides the following features:

- Landmarking (for both coronary and cardiac procedures)
- 3D reconstruction model (for both coronary and cardiac procedures)
- Trace rendering (Smart trace for coronary procedures, and shaft rendering for cardiac procedures)
- 2D fusion (for cardiac procedures)
- 3D measurements (for coronary procedures)
- Quantitative Coronary Angiography (for coronary procedures)

Substantial Equivalence:

The intended use and indications for use of the MediGuide Technology are identical to the intended use and indications for use of its predicate device, the gMPST™ II system. In addition, the same technological characteristics and principles of operation apply for both the MediGuide Technology system and its predicate device.

Performance testing was conducted in order to demonstrate the performance and accuracy of the MediGuide Technology and to verify that all the modifications introduced in the device as compared to its predicate device did not raise any new safety and effectiveness issues.

Test results indicated that the MediGuide Technology is as safe and effective as its predicate device for its intended use and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2012

St. Jude Medical, Inc.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K120301
Trade/Device Name: MediGuide Technology
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II (two)
Product Codes: DQK
Dated: January 31, 2012
Received: January 31, 2012

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

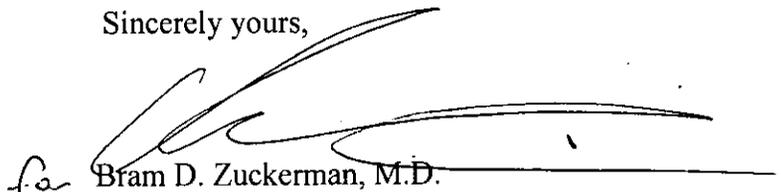
Page 2 – St. Jude Medical, Inc. c/o Mr. Jonathan S. Kahan, Esq.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120301

Device Name: MediGuide Technology

Indications For Use:

The MediGuide Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120301



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

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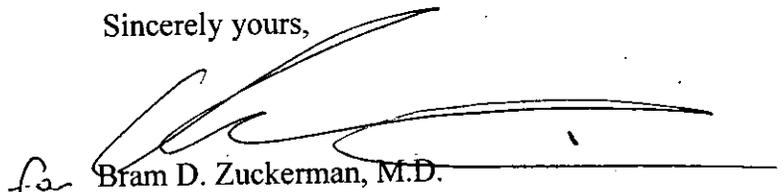
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Director
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Office of Device Evaluation
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Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120301

Sanders, Aisha *

From: Microsoft Outlook
To: 'jonathan.kahan@hoganlovells.com'
Sent: Wednesday, February 01, 2012 9:24 AM
Subject: Relayed: K120301-ACK Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'jonathan.kahan@hoganlovells.com'

Subject: K120301-ACK Letter

Sent by Microsoft Exchange Server 2007



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 01, 2012

ST. JUDE MEDICAL, MEDIGUIDE NAVIGATION SYSTEMS
C/O HOGAN LOVELLS US LLP
COLUMBIA SQUARE
555 THIRTEENTH, NW
WASHINGTON, DISTRICT OF COLUMBIA 20004-1109
ATTN: JONATHAN S. KAHAN

510k Number: K120301

Received: 1/31/2012

Product: MEDIGUIDE TECHNOLOGY

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

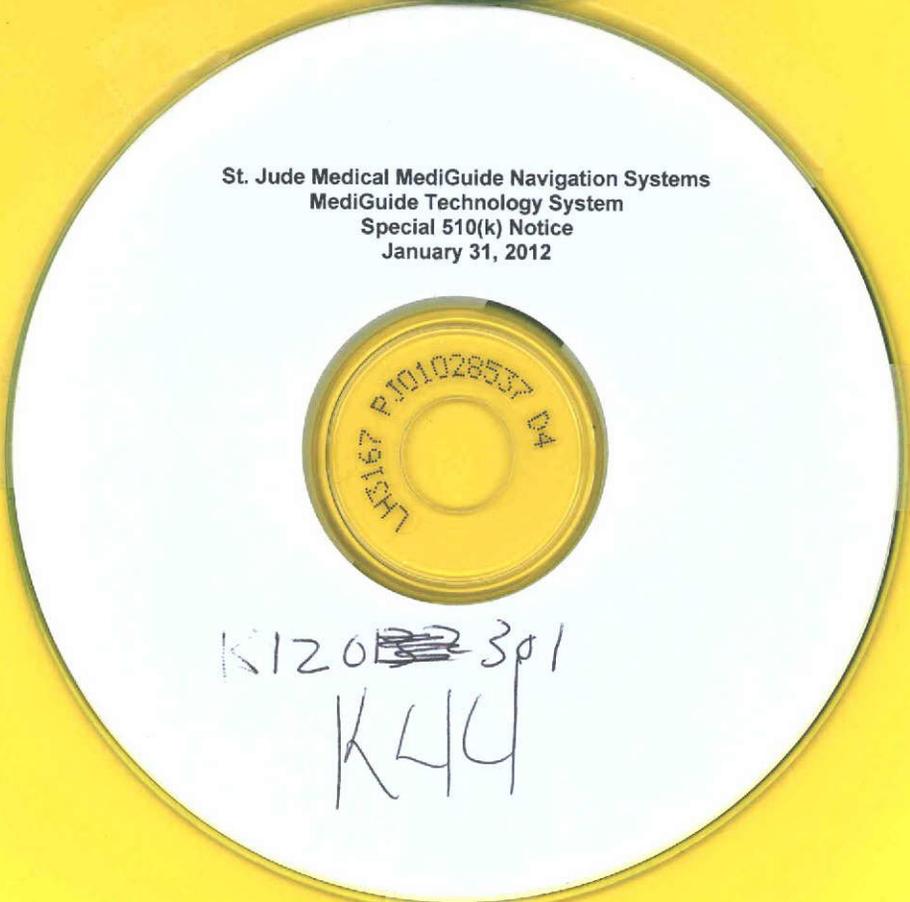
In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

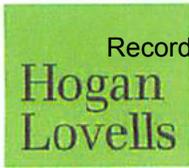
Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff





CY/DID

h120301

Hogan Lovells US LLP
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January 31, 2012

FDA CDRH DMC

JAN 31 2012

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Silver Spring, MD 20993-0002

Attn: Felipe Aguel, Ph.D., Chief, Cardiac Electrophysiology & Monitoring Devices Branch (Room 1312)

Re: **Special 510(k) Submission for the MediGuide Technology System**

Dear Dr. Aguel:

On behalf of our client, St. Jude Medical MediGuide Navigation Systems ("MediGuide" or the "company"), we are submitting the attached Special 510(k) notice to address modifications to the cleared Guided Medical Positioning System II (gMPS™ II) (K102905). This submission addresses

(b)(4)

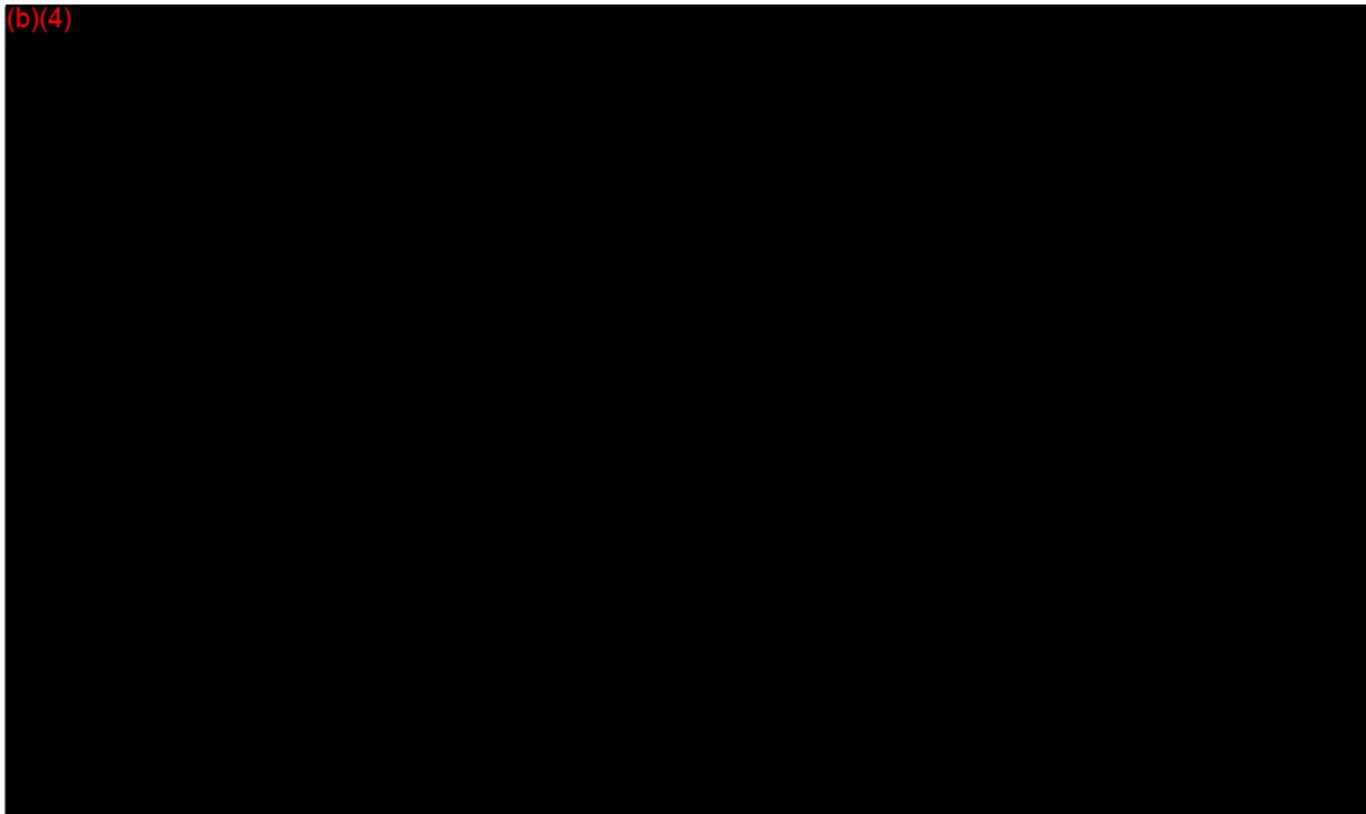
An exact copy of this submission in electronic format is provided on the enclosed CD.

The MediGuide Technology System ("MediGuide Technology System," the "device," or the "system") is used in conjunction with an X-ray System and employs magnetic positioning technology to track a MediGuide enabled diagnostic or therapeutic invasive device for the 3D position relative to any X-Ray image, in real-time or previously recorded cine-loop.

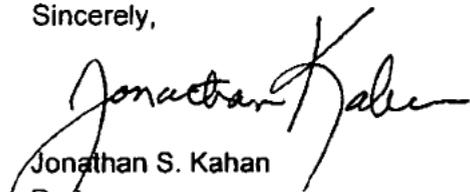
(b)(4)

In accordance with the Food and Drug Administration Amendments Act of 2007, MediGuide has submitted the appropriate application fee. A copy of the User Fee Cover Sheet is provided with the attached Special 510(k) notice.

(b)(4)



Sincerely,



Jonathan S. Kahan

Partner

jonathan.kahan@hoganlovells.com

D +1 202 637 5794

cc: Merav Yarmus, Ph.D., BioMedical Strategy (2004) Ltd.
John Smith, M.D., J.D., Hogan Lovells US LLP
Lina R. Kontos, Hogan Lovells US LLP

Special 510(k) Premarket Notification



MediGuide Ltd.
Advanced Technology Center
POB 15003, Haifa 31053, Israel

January 31, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Felipe Aguel, Ph.D., Chief, Cardiac Electrophysiology & Monitoring Devices Branch (Room 1312)

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Dear Dr. Aguel:

On behalf of our client, St. Jude Medical MediGuide Navigation Systems ("MediGuide" or the "company"), we are submitting the attached Special 510(k) notice to address modifications to the cleared Guided Medical Positioning System II (gMPS™ II) (K102905). This submission addresses

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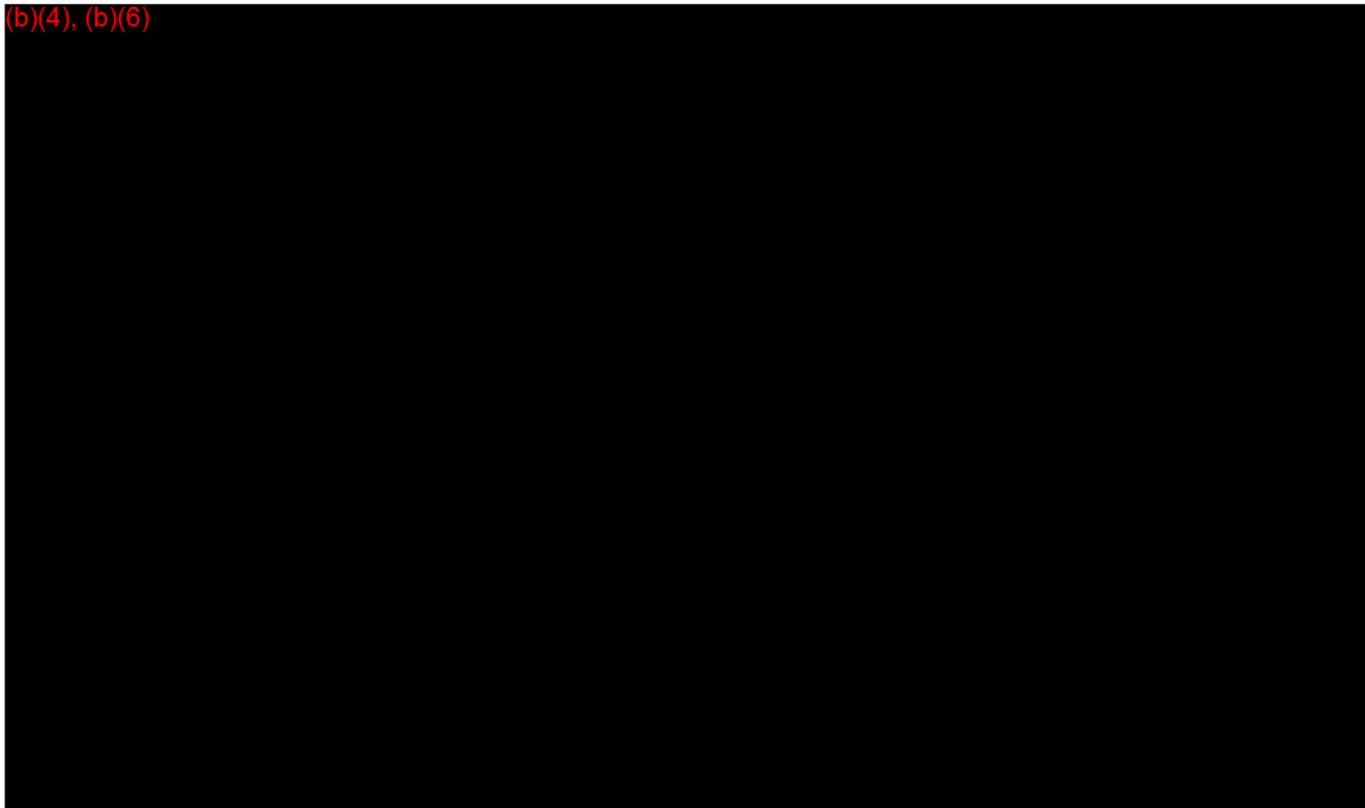
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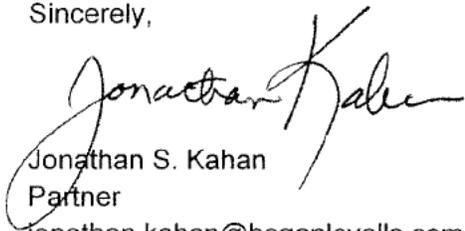
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(b)(4), (b)(6)



Sincerely,



Jonathan S. Kahan

Partner

jonathan.kahan@hoganlovells.com

D +1 202 637 5794

cc: Merav Yarmus, Ph.D., BioMedical Strategy (2004) Ltd.
John Smith, M.D., J.D., Hogan Lovells US LLP
Lina R. Kontos, Hogan Lovells US LLP

CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.		
Date of Submission 01/31/2012	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)		
SECTION A		TYPE OF SUBMISSION		
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name St. Jude Medical, Mediguide Navigation Systems		Establishment Registration Number (if known) 2184149		
Division Name (if applicable)		Phone Number (including area code) (b)(4)		
Street Address Advanced technology Center		FAX Number (including area code) (b)(4)		
City Haifa	State / Province	ZIP/Postal Code 15003	Country Israel	
Contact Name (b)(6)				
Contact Title (b)(4)		Contact E-mail Address (b)(4)		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name Hogan Lovells US LLP				
Division Name (if applicable)		Phone Number (including area code) (202) 637-5794		
Street Address Columbia Square 555 Thirteenth, NW		FAX Number (including area code) (202) 637-5910		
City Washington	State / Province DC	ZIP Code 20004-1109	Country USA	
Contact Name Jonathan S. Kahan, ESQ				
Contact Title RA Consultant		Contact E-mail Address jonathan.kahan@hoganlovells.com		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		
SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		
SECTION D3 REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (specify): Modification to the cleared gMPS II system, including changes in software, but without any change in technology		

SECTION E								ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS																															
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information																															
1	DQK	2		3		4		<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement																															
5		6		7		8																																	
Information on devices to which substantial equivalence is claimed (if known)																																							
<i>510(k) Number</i>		<i>Trade or Proprietary or Model Name</i>				<i>Manufacturer</i>																																	
1	K102905	1	Guided Medical Positioning System II (gMPS II)				1	St. Jude Medical, MediGuide Navigation Systems																															
2		2					2																																
3		3					3																																
4		4					4																																
5		5					5																																
6		6					6																																
SECTION F										PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS																													
Common or usual name or classification name																																							
<i>Trade or Proprietary or Model Name for This Device</i>										<i>Model Number</i>																													
1	MediGuide Technology									1	MG1000																												
2										2																													
3										3																													
4										4																													
5										5																													
FDA document numbers of all prior related submissions (regardless of outcome)																																							
1	2	3	4	5	6	7	8	9	10	11	12																												
Data Included in Submission																																							
<input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials																																							
SECTION G																				PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS																			
Product Code					C.F.R. Section (if applicable)					Device Class																													
DQK					870.1425					<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified																													
Classification Panel																																							
Indications (from labeling)																																							
The MediGuide Technology is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.																																							

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name St. Jude Medical, Inc.		Establishment Registration Number 2184149	
Division Name (if applicable)		Phone Number (including area code) +1-651-7562000	
Street Address One St. Jude Medical Drive		FAX Number (including area code) +1-651-7563301	
City St. Paul, MN		State / Province MN	ZIP Code 55117
		Country USA	
Contact Name (b)(6)	Contact Title (b)(4)	Contact E-mail Address (b)(4)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code
			Country
Contact Name	Contact Title	Contact E-mail Address	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code
			Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	█	█	(b)(4) █	█	
2	(b)(4) █	█	█	█	
3	(b)(4) █	█	█	█	
4					
5					
6					
7					
Please include any additional standards to be cited on a separate page.					
<p>Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>					

<u>ITEM</u>	<u>COMMENT</u>
1. Device trade or proprietary name	<i>See</i> Special 510(k) notice sections 1 and 2
2. Device common or usual name or classification name	<i>See</i> Special 510(k) notice section 1
3. Establishment registration number (only applies if establishment is registered)	2184149
4. Class into which the device is classified	<i>See</i> Special 510(k) notice section 1
5. Classification Panel	<i>See</i> Attachment 1-3
6. Action taken to comply with Section 514 of the Act	Not Applicable
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use	<i>See</i> Special 510(k) notice section 4 and its attachment
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	<i>See</i> Attachment 1-3
9. For class III devices only, a class III certification and a class III summary	Not Applicable
10. Photographs and engineering drawings of the device	<i>See</i> Special 510(k) notice section 2
11. The marketed device(s) to which equivalence is claimed including labeling and description of the device	<i>See</i> Special 510(k) notice section 3
12. Statement of similarities and/or differences with marketed devices(s)	<i>See</i> Special 510(k) notice section 3 and its attachment
13. Data to show consequences and effects of a modified device	<i>See</i> Special 510(k) notice section 5
14. Submitter's name and address	<i>See</i> Special 510(k) notice section 1
15. Contact person, telephone number and fax number	<i>See</i> Special 510(k) notice section 1 and Attachment 1-3
16. Representative/Consultant if applicable	<i>See</i> Special 510(k) notice section 1 and Attachment 1-3

17. Table of Contents with pagination	<i>See</i> Special 510(k) notice page i
18. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	<i>See</i> CDRH Premarket Review Cover Sheet
19. Comparison table of the new device to the marketed device(s)	<i>See</i> Attachment 3-1
20. Action taken to comply with voluntary standards and Standards Data Report Form for 510(k)s	Not Applicable
21. Performance data	
a. bench testing	<i>See</i> Special 510(k) notice section 5 and Attachment 5-3
b. animal testing	Not applicable
c. clinical data	Not applicable
d. Certification of Compliance with the Requirements of ClinicalTrials.gov data bank	<i>See</i> Special 510(k) notice section 1 and Attachment 1-5
22. Sterilization/shelf life information	Not applicable
23. Software Information	<i>See</i> Special 510(k) notice section 8 and its attachments
24. Hardware information	<i>See</i> Special 510(k) notice section 2
25. Is this device subject to issues that have been addressed in specific guidance document(s)?	No
26. Other (specify) Biocompatibility Certification/Information	None
27. Declaration of Conformance to Design Control	<i>See</i> Special 510(k) notice Section 5 and Attachment 5-1

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LIST OF ATTACHMENTS

Attachment Number and Name	Section No.
1-1 Truthful and Accurate Statement	Section 1
1-2 Indication for Use Statement	Section 1
1-3 510(k) Summary	Section 1
1-4 MDUFMA User Fee Cover Sheet	Section 1
1-5 Certification of Compliance with ClinicalTrials.gov	Section 1
3-1 Substantial Equivalence Comparison Table	Section 3
4-1 User's Manual	Section 4
5-1 Declaration of Conformity with Design Controls and Manufacturing Facility	Section 5
5-2 Bench Testing Results	Section 5

(b)(4)



Section 8

Section 8

Section 8

Section 8

Section 8

1 **GENERAL INFORMATION**

1.1 **APPLICANT'S NAME**

St. Jude Medical
MediGuide Navigation Systems
Advanced Technology Center,
POB 15003, Haifa, Israel
Tel: +972-4-8137000
Fax: +972-4-8550412

1.2 **CONTACT PERSON**

Jonathan S. Kahan, Esq.
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Tel: (202) 637-5794
Fax: (202) 637-5910
Mail: jonathan.kahan@hoganlovells.com

And/Or

Merav Yarmus, Ph.D.
BioMedical Strategy (2004) Ltd.
7 Jabotinsky Street.
Ramat Gan 52520, Israel
Tel: +972-3- 6123281
Fax: +972-3-6123282
Mail: merav@ebms.co.il

1.3 **TRADE NAME**

MediGuide Technology

1.4 **CLASSIFICATIONS NAME**

Programmable diagnostic computer (DQK, Class II)

1.5 MANUFACTURER

St. Jude Medical, Inc.
One St. Jude Medical Drive
St. Paul, MN 55117
USA
Tel: +1-651-7562000
Fax: +1-651-7563301

1.6 ESTABLISHMENT REGISTRATION NO.

2184149

1.7 IDENTIFICATION OF LEGALLY MARKETED DEVICE

Guided Medical Positioning System II (gMPS™ II) cleared under K102905

1.8 REASON FOR SUBMISSION

A special 510(k) is submitted for the modifications made to the cleared Guided Medical Positioning System II (gMPS™ II).

St. Jude Medical - MediGuide Navigation Systems (hereinafter MediGuide) will market the device containing these modifications under the trade name MediGuide Technology.

1.9 TRUTHFUL AND ACCURATE STATEMENT

A 510(k) Truthful and Accurate Statement in accordance with 21 CFR 807.87 (j) is attached to this section (Attachment 1-1).

1.10 INTENDED USE AND INDICATIONS FOR USE STATEMENT

The MediGuide Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

This is the **same intended use** as previously cleared for the gMPS™ II system, except for the change in the name of the system.

Draft labeling, including proposed labels and User's Manual, are provided in Section 4 of this submission.

An Indications for Use Statement is attached to this section (Attachment 1-2).

1.11 510(K) SUMMARY

A 510(k) Summary (attached to this section, Attachment 1-3) is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990. This 510(k) Summary meets the requirements identified in 21 CFR 807.92.

1.12 CONFIDENTIALITY

St. Jude Medical MediGuide Navigation Systems considers its intent to market the MediGuide Technology to be confidential commercial information.

The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising and law firms, and its consultants. The Company, therefore, requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

1.13 USER FEE

The Company has remitted the Medical Device User Fee of (b)(4)

The payment identification Number is (b)(4).

A copy of the Medical Device User Fee Cover Page is attached to this section (Attachment 1-4).

1.14 COMPLIANCE WITH CLINICALTRIALS.GOV

Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) is attached to this section (Attachment 1-5).

ATTACHMENTS TO SECTION 1

- 1-1 Truthful and Accurate Statement**
- 1-2 Indications for Use Statement**
- 1-3 510(k) Summary**
- 1-4 MDUFMA Medical Device User Fee Cover Sheet**
- 1-5 Certification of Compliance with ClinicalTrials.gov**

ATTACHMENT 1-1

Truthful and Accurate Statement

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Sr. VP Technology & Site Manager of

St. Jude Medical – MediGuide Navigation Systems, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the MediGuide Technology are truthful and accurate and that no material fact has been omitted.

(b)(6)

(Signature)

(b)(6)

(Typed Name)

(b)(4)

(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

ATTACHMENT 1-2

Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: MediGuide Technology

Indications For Use:

The MediGuide Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ATTACHMENT 1-3

510(k) Summary

510(K) SUMMARY

510(K) Number K_____

Applicant's Name:

St. Jude Medical
MediGuide Navigation Systems
Advanced Technology Center, POB 15003, Haifa, Israel
Tel: +972-4-8137000
Fax: +972-4-8550412

Contact Person:

Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Tel: (202) 637-5794
Fax: (202) 637-5910
Mail: jonathan.kahan@hoganlovells.com

And/Or

Merav Yarmus, Ph.D.
Biomedical Strategy (2004) Ltd.
7 Jabotinsky Street.
Ramat Gan 52520, Israel
Tel: +972-3- 6123281
Fax: +972-3-6123282
Mail: merav@ebms.co.il

Date Prepared:

January, 2012

Trade Name:

MediGuide Technology

Classification Name:

Programmable diagnostic computer

Product Code:

DQK

Device Class:

II

Regulation Number:

870.1425

Panel:

Cardiovascular

Predicate Devices:

Guided Medical Positioning System II (gMPS™ II) [MediGuide Ltd.] cleared under K102905.

Intended Use / Indications for Use:

The MediGuide Technology System is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

Device Description:

The MediGuide Technology System, used in conjunction with an X-ray System, employs magnetic positioning technology to track a MediGuide enabled diagnostic or therapeutic invasive device for the 3D position relative to any X-Ray image, in real-time or previously recorded cine-loop.

The MediGuide Technology System includes two optional software packages. The Coronary package includes the Coronary application, and it supports coronary procedures. The Cardiac package includes the Cardiac Navigation application and the Cardiac Navigation with Angio Survey™ application, both support cardiac procedures.

The most fundamental capability of the MediGuide Technology is the positioning and navigation of MediGuide enabled devices. This feature enables projection of the real time position of a MediGuide sensor (and thus of the MediGuide enabled device) on real time 2D X-Ray images (live mode) or in a recorded mode (the MediGuide enabled device tip real time position is superimposed on a previously recorded cine loop or still image). The MediGuide Technology enables simultaneous tracking of up to three MediGuide enabled devices.

In addition, the MediGuide Technology provides the following features:

- Landmarking (for both coronary and cardiac procedures)
- 3D reconstruction model (for both coronary and cardiac procedures)
- Trace rendering (Smart trace for coronary procedures, and shaft rendering for cardiac procedures)
- 2D fusion (for cardiac procedures)
- 3D measurements (for coronary procedures)
- Quantitative Coronary Angiography (for coronary procedures)

Substantial Equivalence:

The intended use and indications for use of the MediGuide Technology are identical to the intended use and indications for use of its predicate device, the gMPS™ II system. In addition, the same technological characteristics and principles of operation apply for both the MediGuide Technology system and its predicate device.

Performance testing was conducted in order to demonstrate the performance and accuracy of the MediGuide Technology and to verify that all the modifications introduced in the device as compared to its predicate device did not raise any new safety and effectiveness issues.

Test results indicated that the MediGuide Technology is as safe and effective as its predicate device for its intended use and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.

ATTACHMENT 1-4

MDUFMA Medical Device User Fee Cover Sheet

Records processed under FOIA Request # 2015-3986; Released by CDRH on 09-30-2015

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) MEDIGUIDE LTD P.O. Box 15003 +972-4-8137038 +972-4-8137000 Haifa 31053 IL 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)		2. CONTACT NAME Amir Straschnow 2.1 E-MAIL ADDRESS astraschnow@sjm.com 2.2 TELEPHONE NUMBER (include Area code) 972-4-8137038 2.3 FACSIMILE (FAX) NUMBER (Include Area code) +972-4-8550412	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) <u>Select an application type:</u>			
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		19-Dec-2011	

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

https://userfees.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.jsp?vname=Amir%20... 19/12/2011

ATTACHMENT 1-5

Certification of Compliance with ClinicalTrials.gov



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER St. Jude Medical - MediGuide Navigation Systems	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Jan 31, 2012
3. ADDRESS (Number, Street, State, and ZIP Code) Advanced Technology Center, POB 15003, Haifa, Israel	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 972-4-8137000 (Fax) 972-4-8550412

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

MediGuide Technology

Programmable diagnostic computer

21 CFR 870.1425

DQK, Class II

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
 IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) (b)(6)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) (b)(6) (Title) (b)(4)
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) Advanced Technology Center, POB 15003, Haifa, Israel	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 972-4-8137000 (Fax) 972-4-8550412
	15. DATE OF CERTIFICATION Jan 31, 2012

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.
Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.
Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

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Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

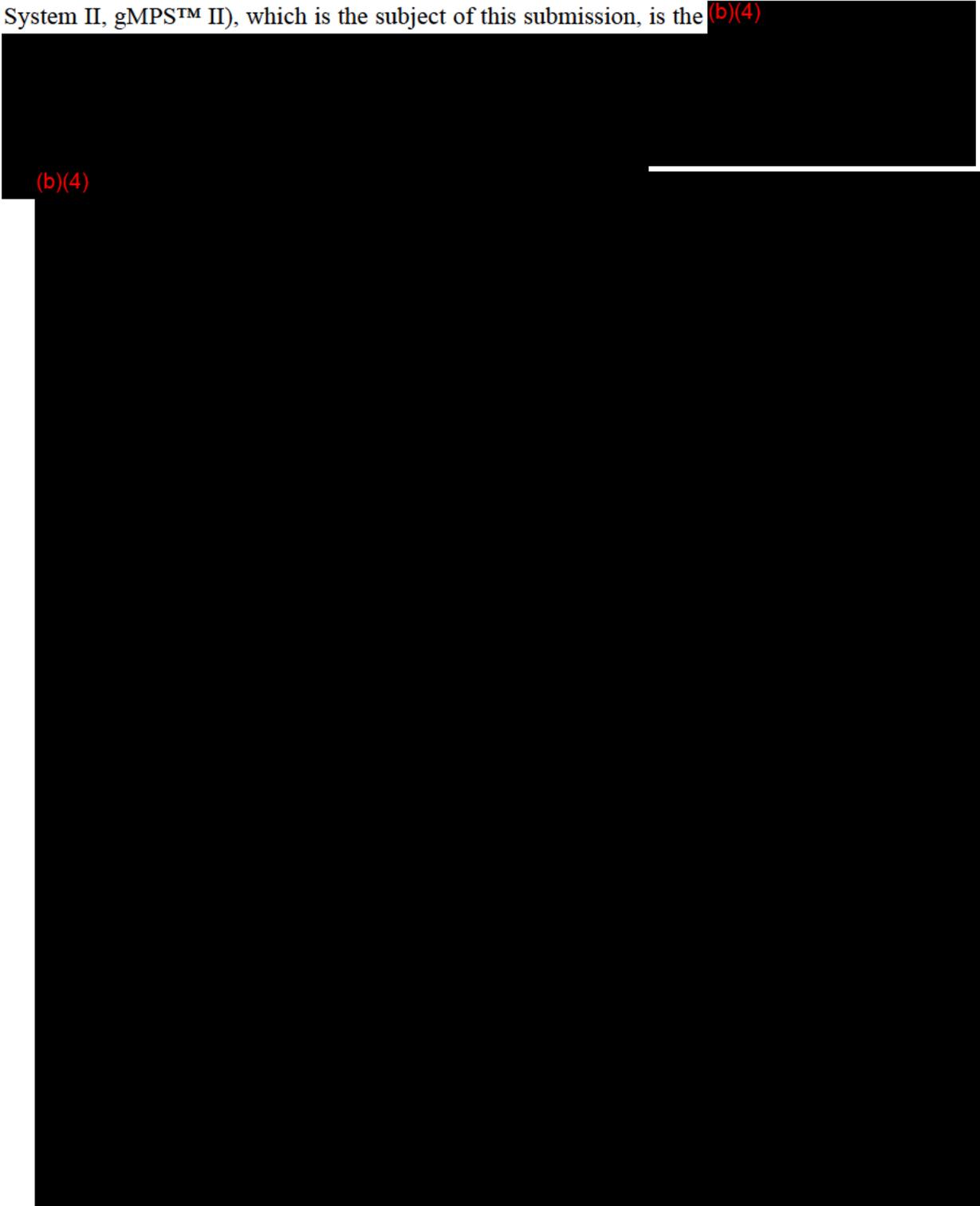
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Form FDA 3674 (11/08) (BACK)

2 DESCRIPTION OF THE MODIFIED DEVICE

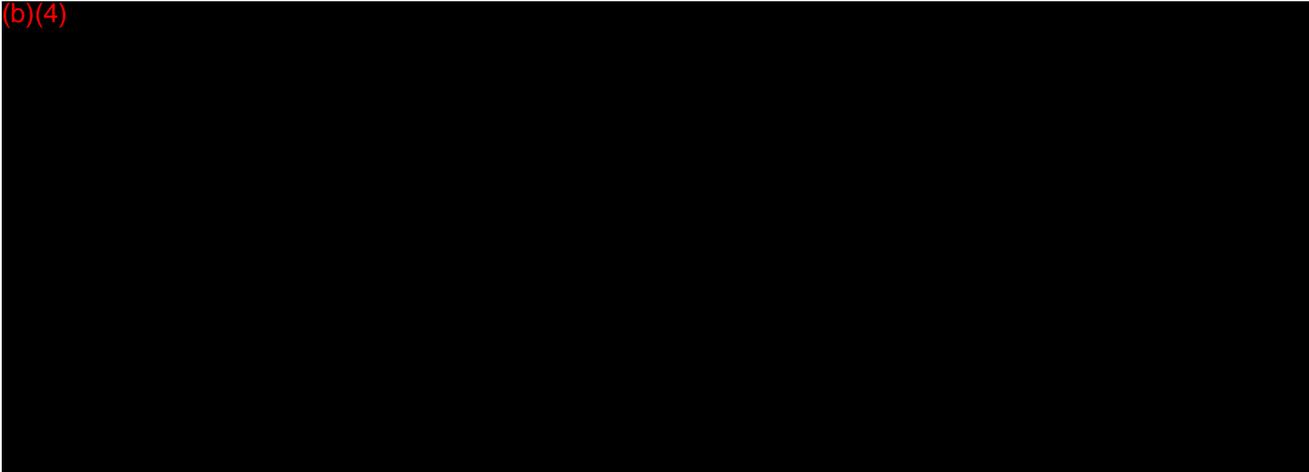
2.1 INTRODUCTION

The MediGuide Technology system (previously referred to as Guided Medical Positioning System II, gMPS™ II), which is the subject of this submission, is the (b)(4)



(b)(4)

(b)(4)



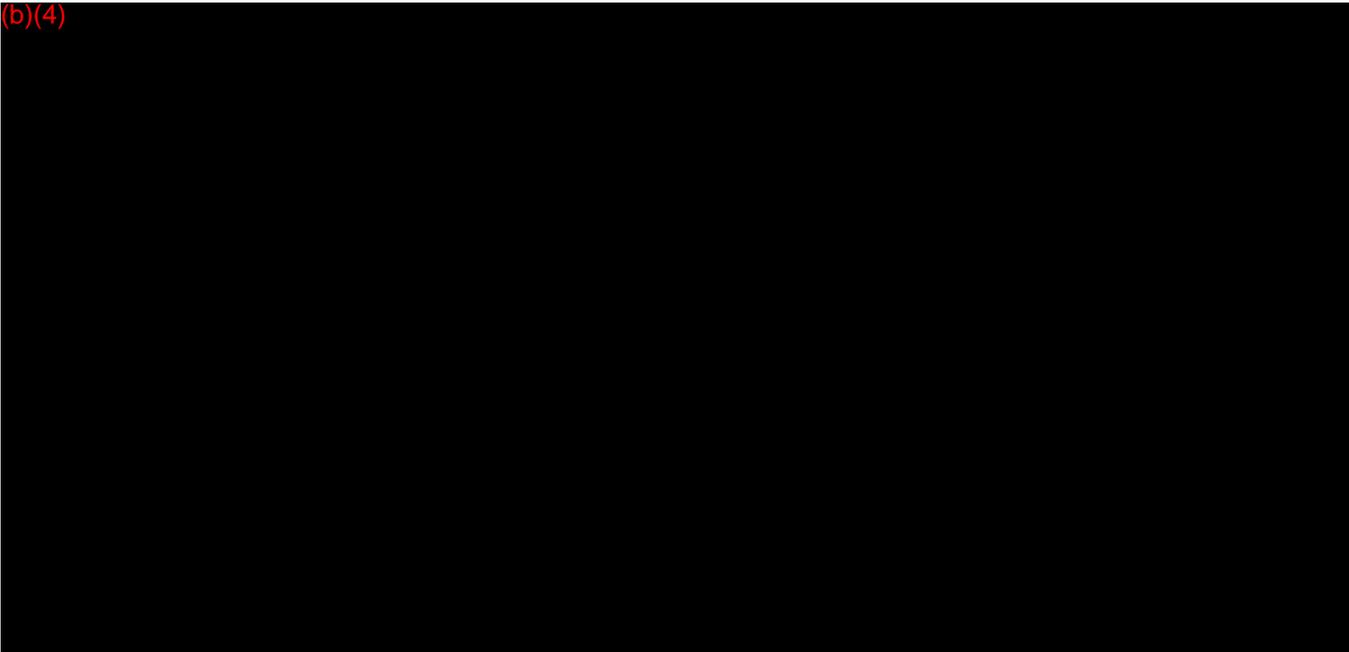
2.2 INDICATIONS FOR USE

The following is the Indications for Use statement for the modified MediGuide Technology system. The intended use statement is identical to the cleared system (K102905), except for the change in the name of the system:

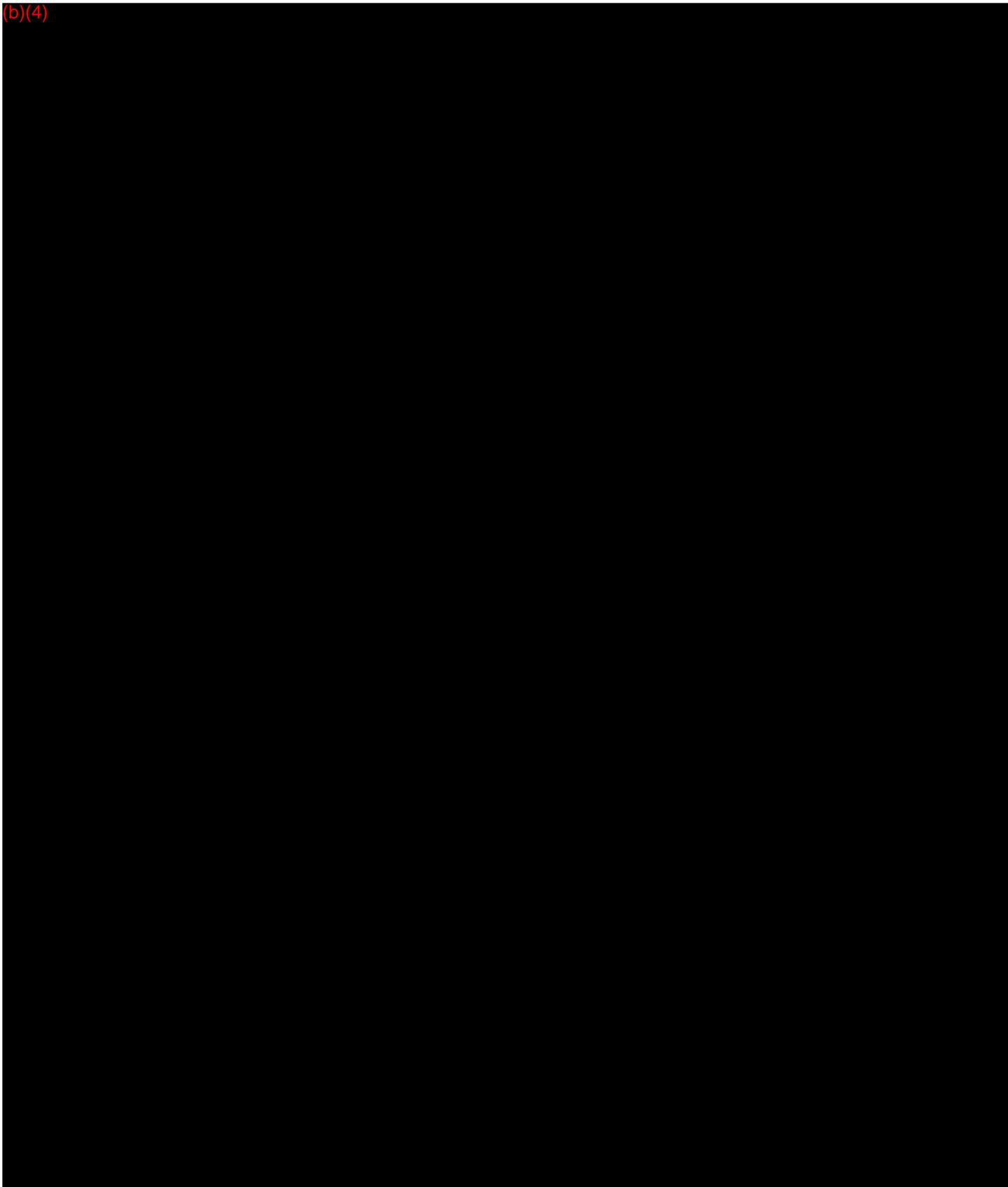
The MediGuide Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

2.3 GENERAL DESCRIPTION

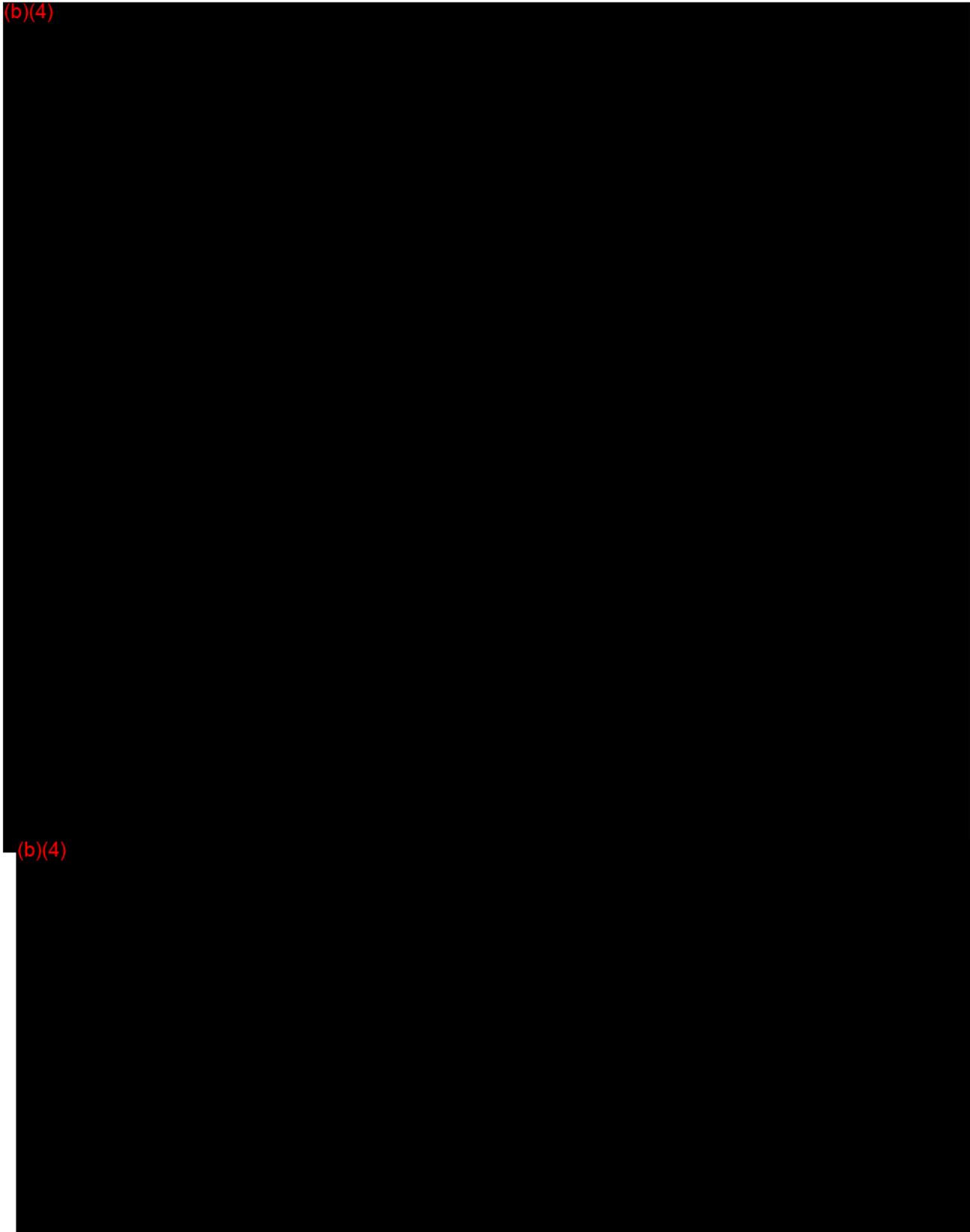
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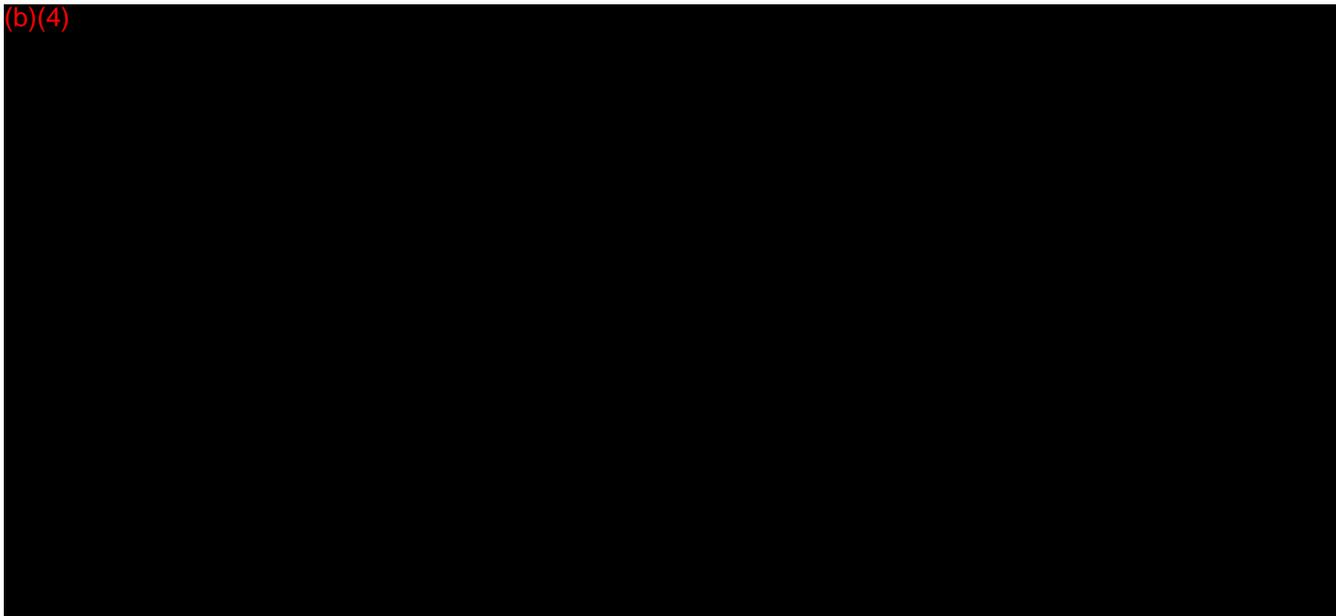


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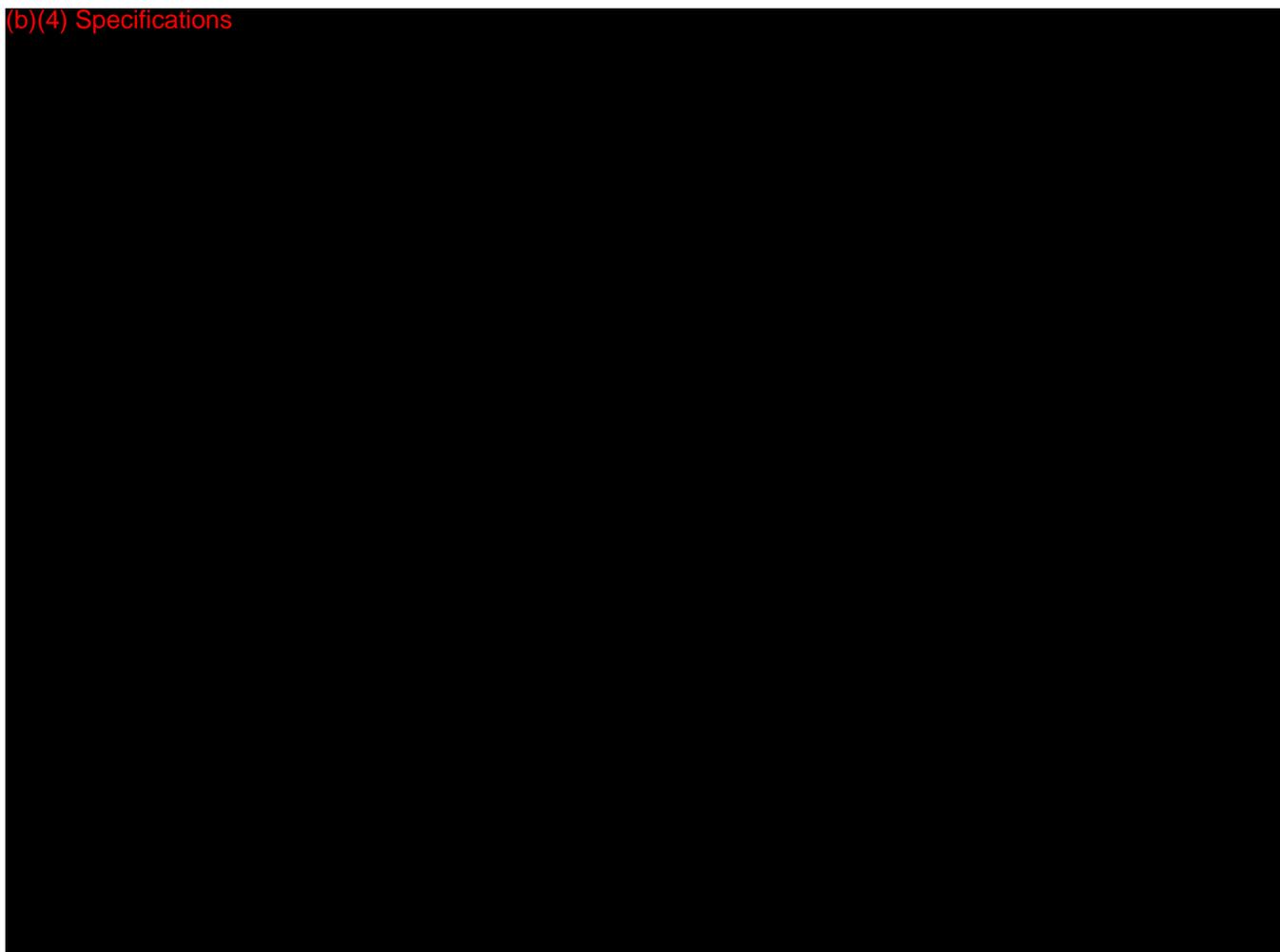


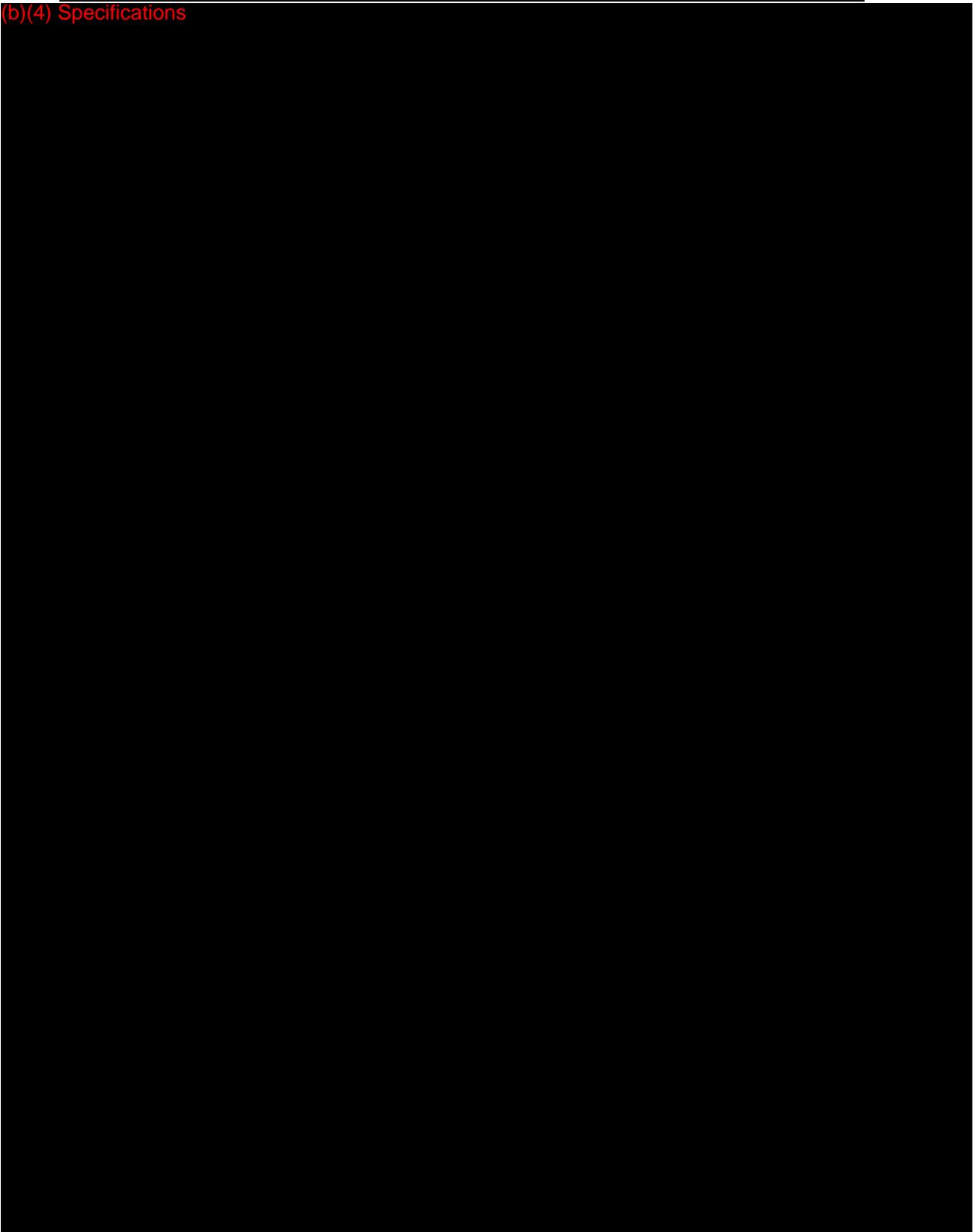
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(b)(4)



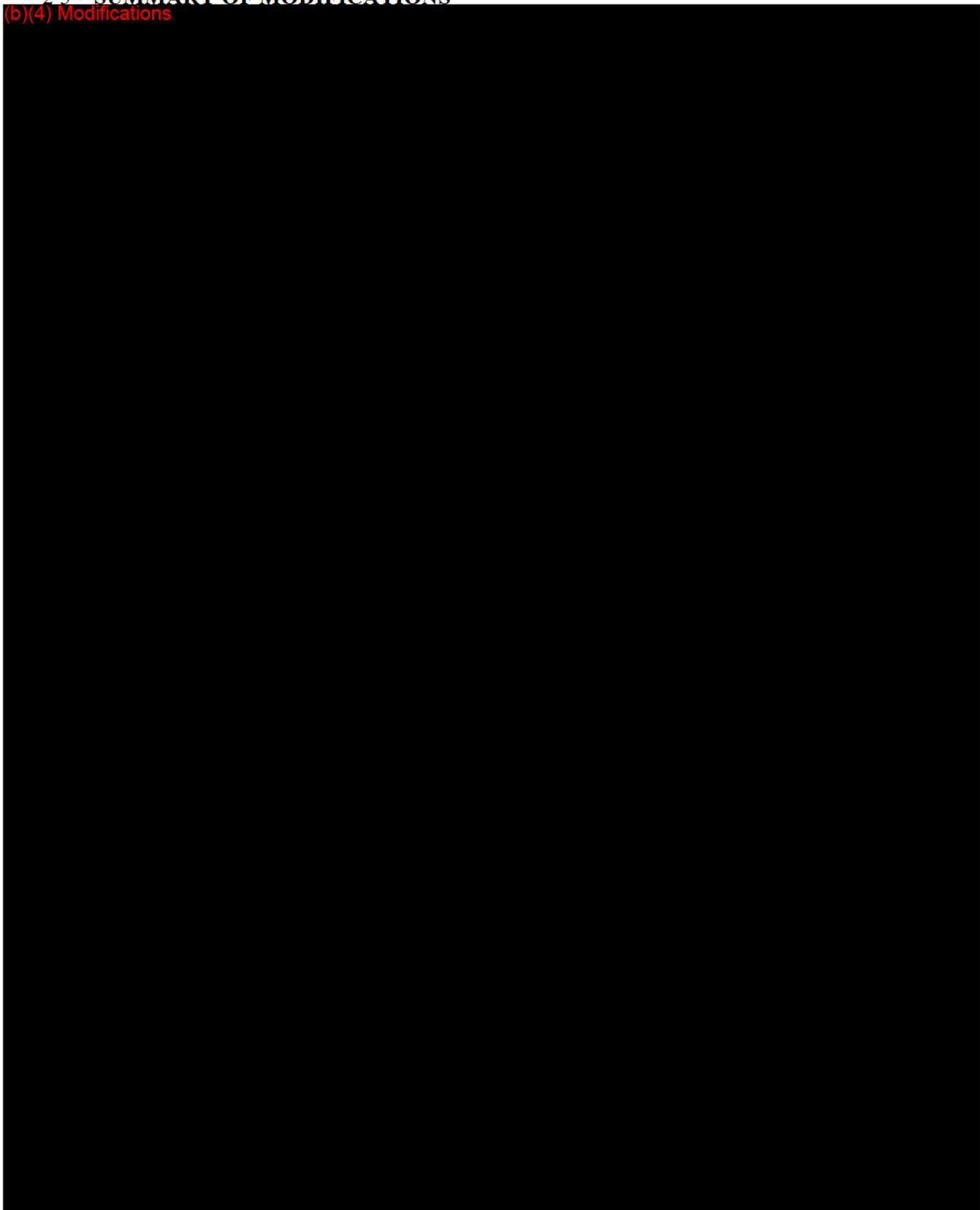
(b)(4) Specifications



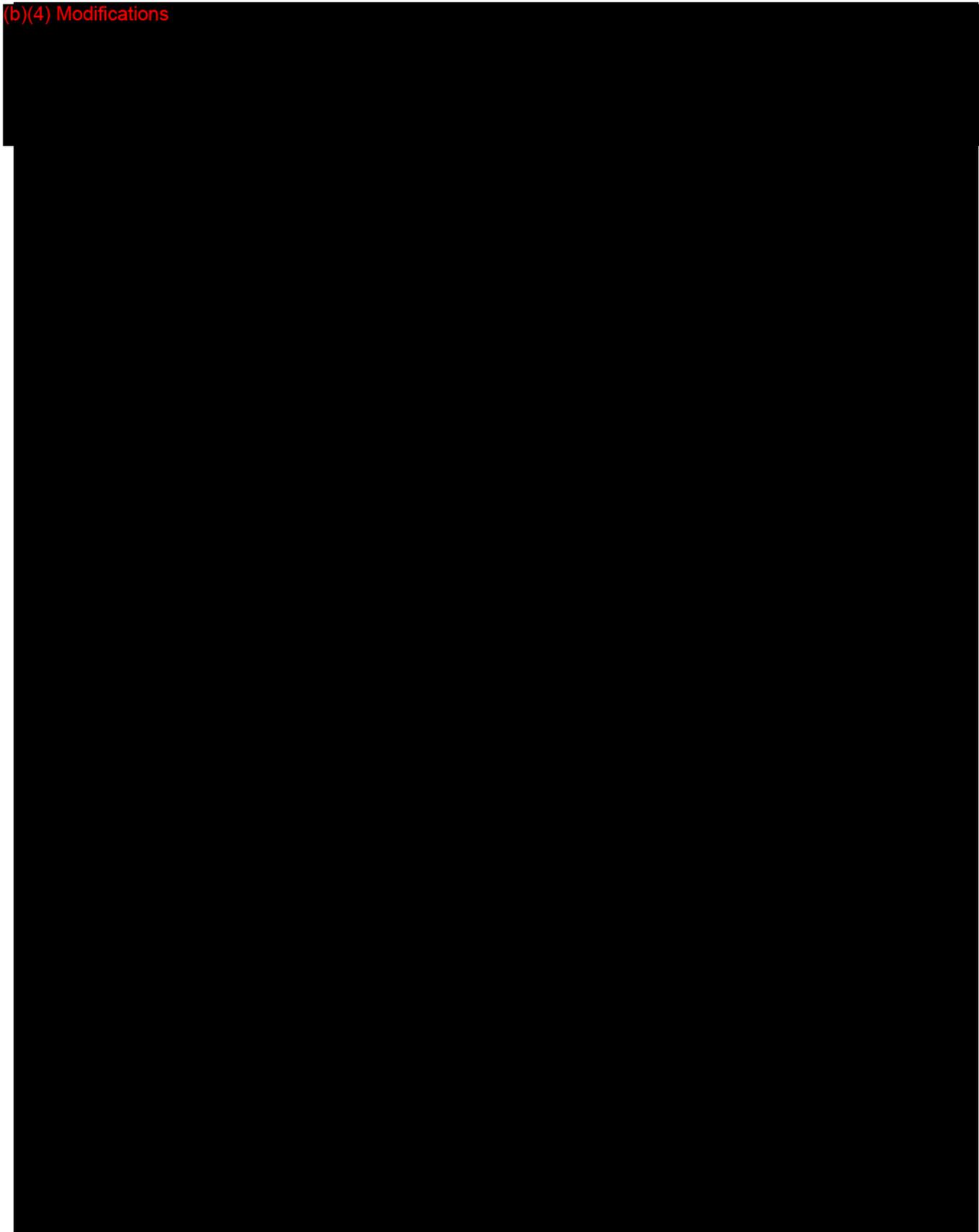
Type	Parameter	Value
<p>(b)(4) Specifications</p> 		

2.5 SUMMARY OF MODIFICATIONS

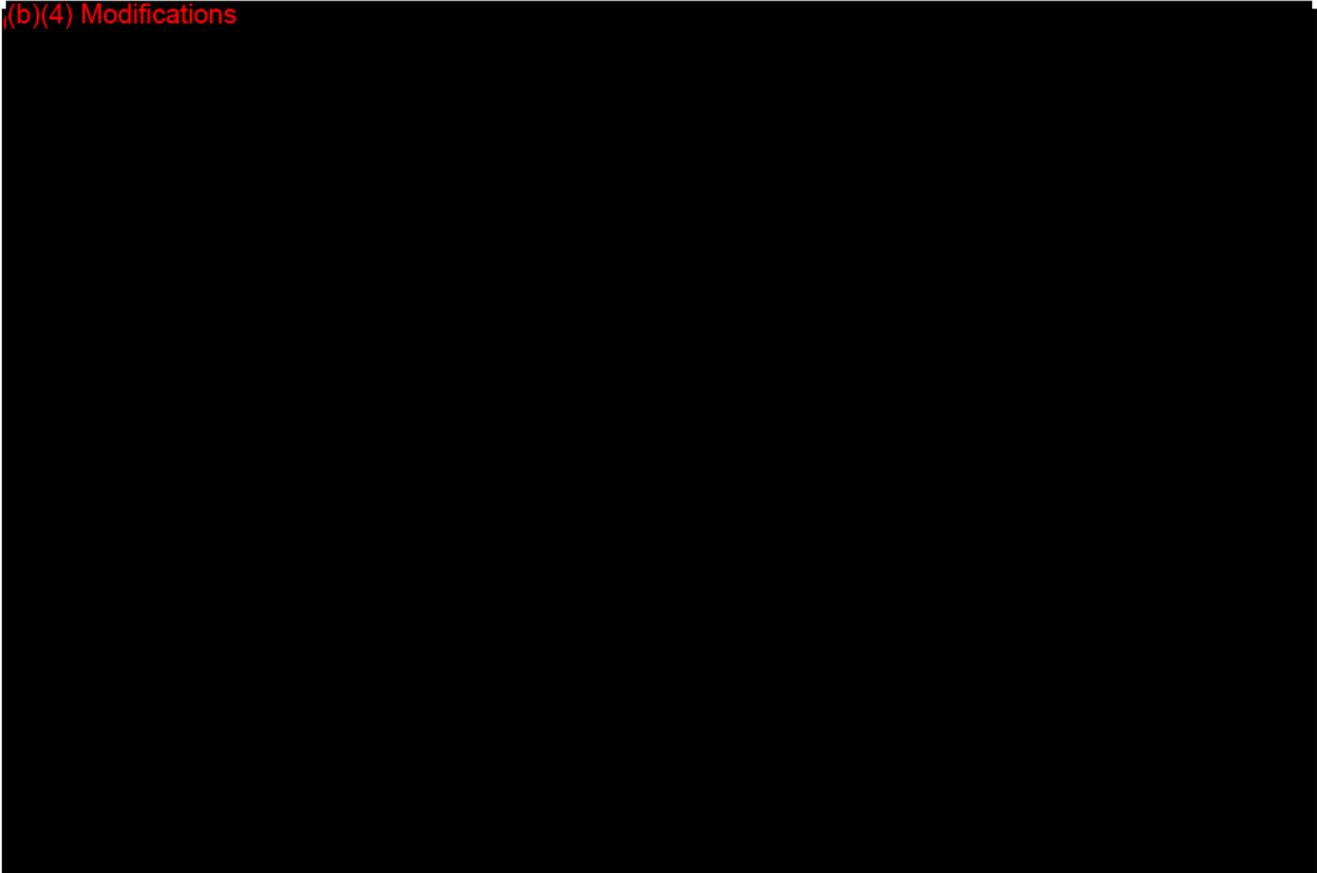
(b)(4) Modifications



(b)(4) Modifications



(b)(4) Modifications



3 **SUBSTANTIAL EQUIVALENCE RATIONALE**

3.1 **INTENDED USE AND INDICATIONS FOR USE**

Both the cleared and modified MediGuide Technology systems claim for the same identical intended use, except for the change in the name of the system.

The MediGuide Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide-enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The system is indicated for use as an adjunct to fluoroscopy.

3.2 **TECHNOLOGICAL CHARACTERISTICS**

(b)(4)

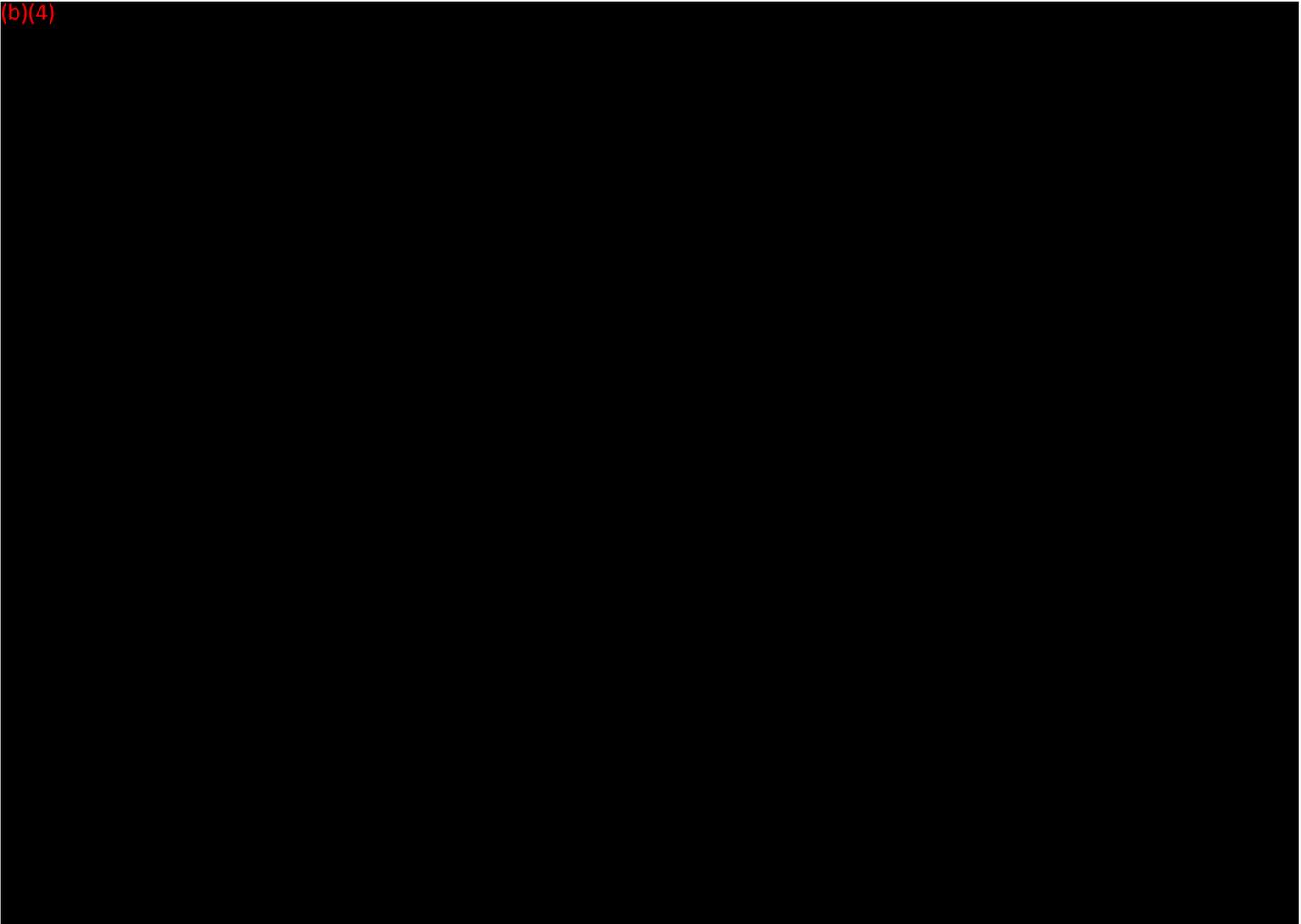
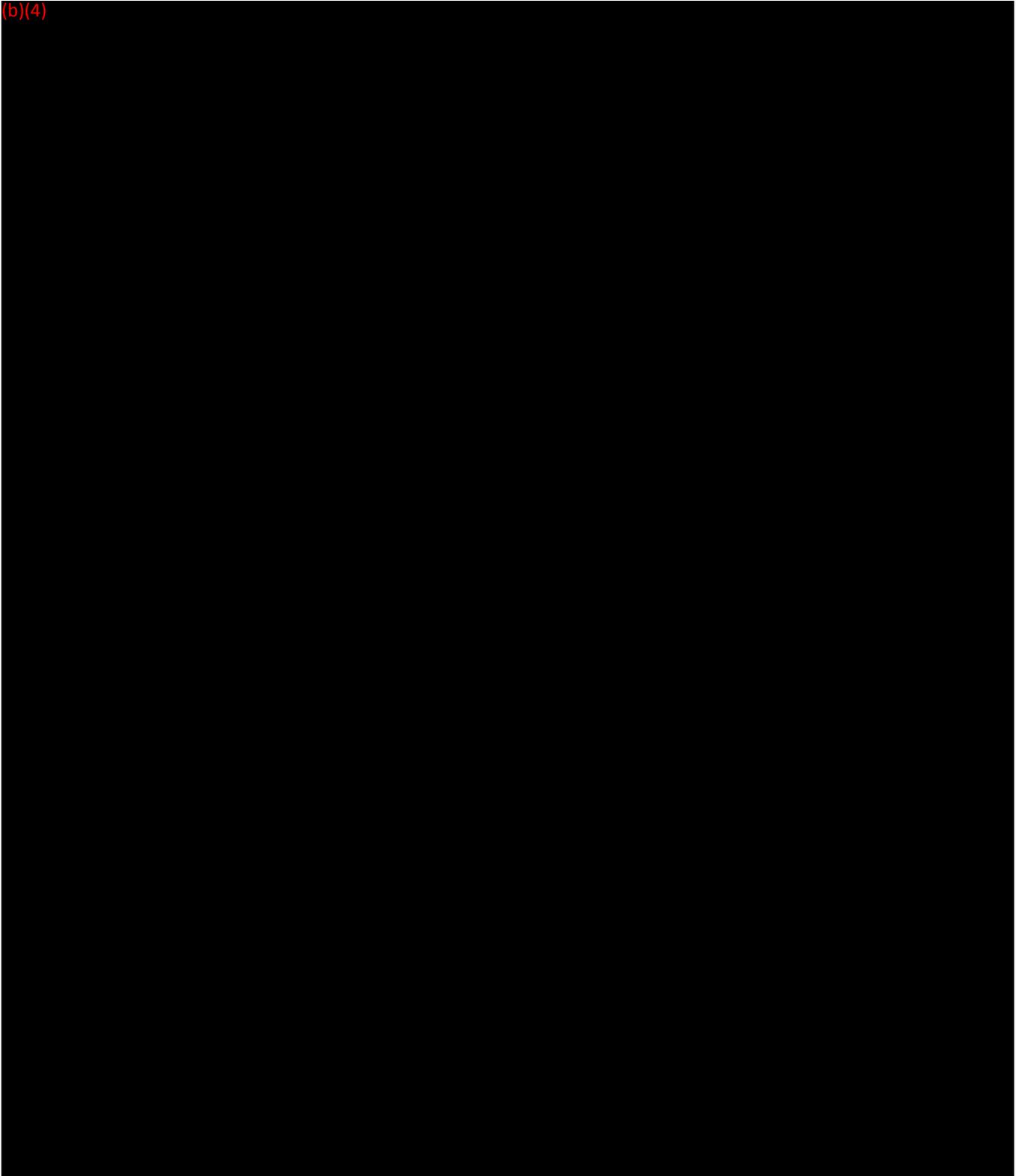
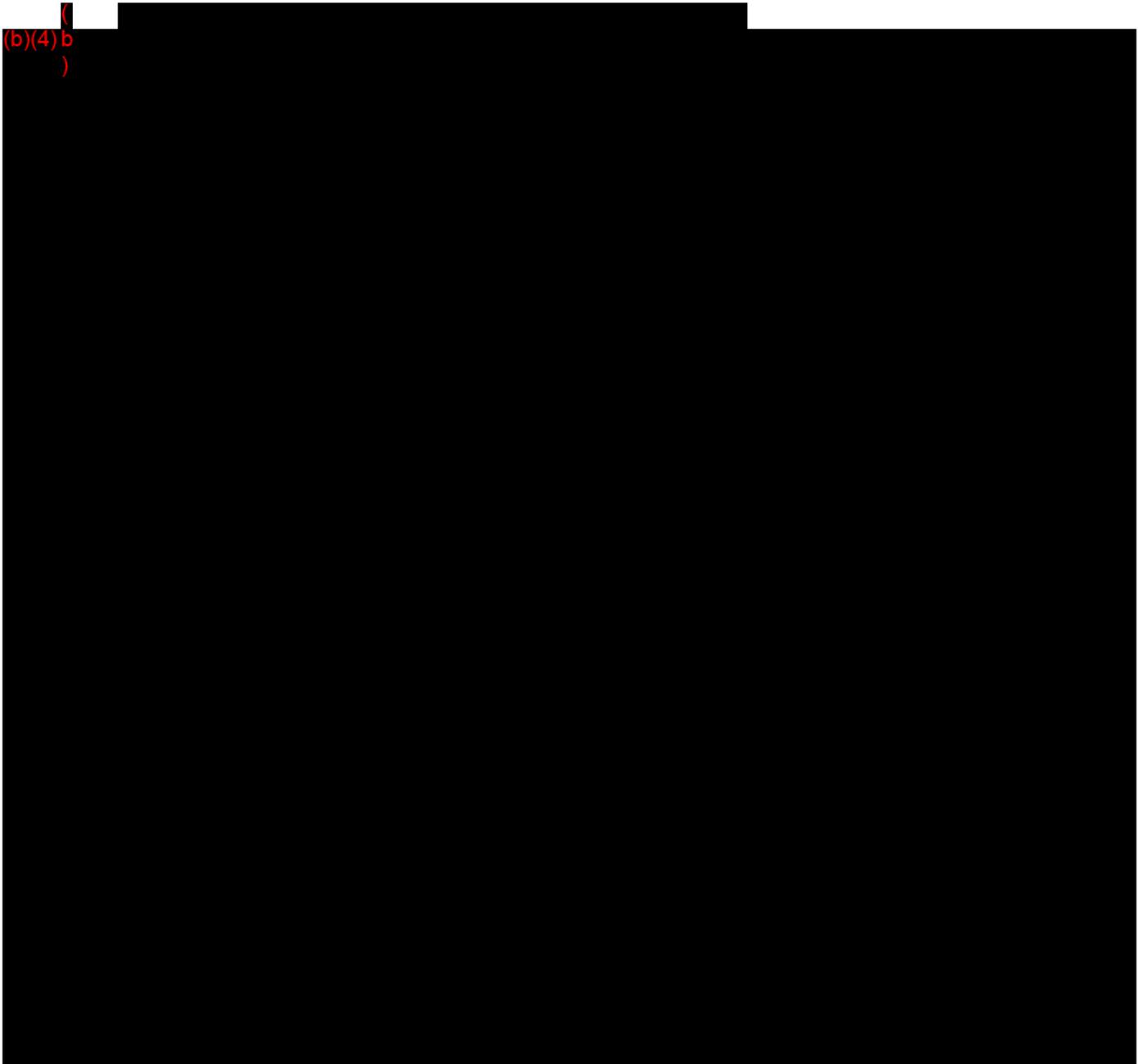


Table 3-1. Comparison between type of software components and their functionality in the cleared and modified MediGuide systems.

(b)(4)





(b)(4) b
)

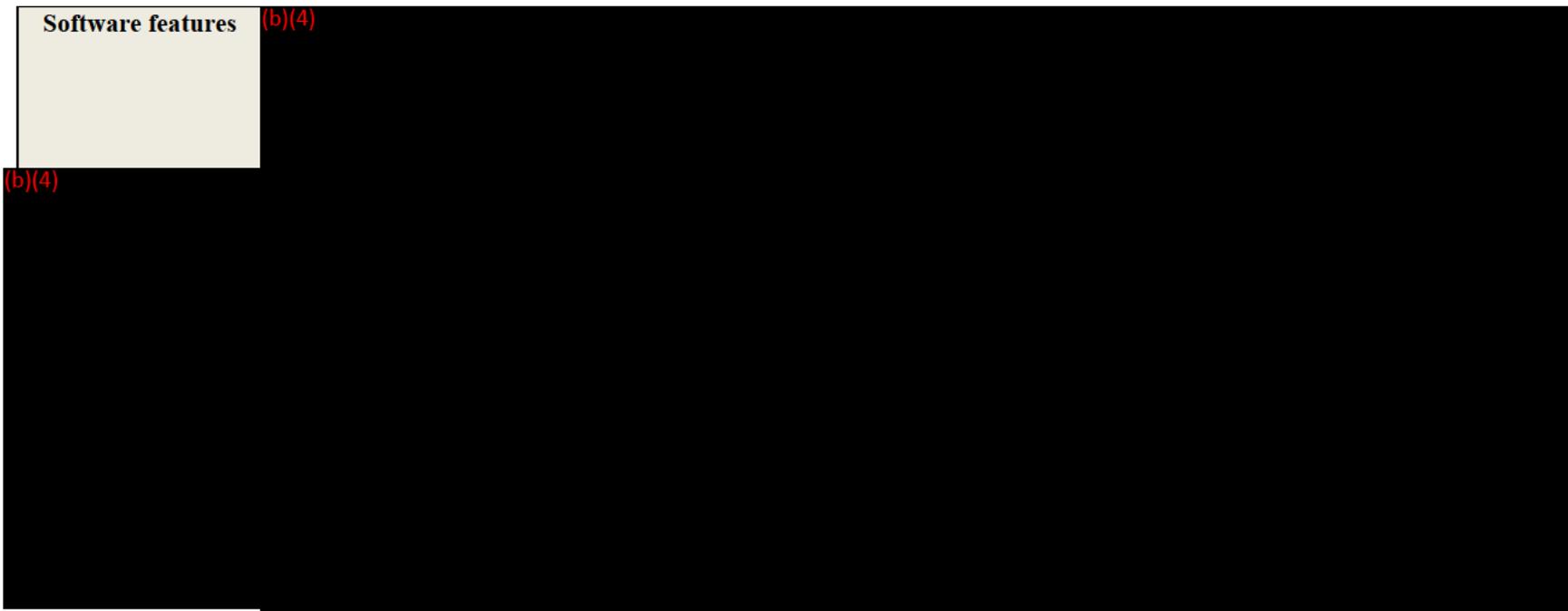
Table 3-2. Comparison between User applications in the cleared and modified MediGuide Technology systems.

Software features	(b)(4)
(b)(4)	(b)(4)

Software features

(b)(4)

(b)(4)



As described above and presented in Table 3-2, (b)(4)

[Redacted]

(b)(4)

[Redacted]

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(b)(4)

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(b)(4)

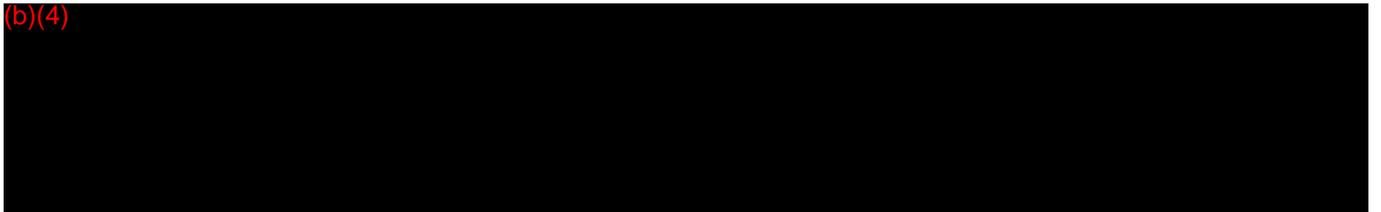
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(b)(4)



3.3 PRINCIPLES OF OPERATION

(b)(4)



(b)(4)

(b)(4)

3.4 PERFORMANCE

The following design control activities were performed in order to verify that the modified MediGuide Technology system has comparable performance and safety as compared to the cleared device:

(b)(4)

3.5 SUMMARY

These modifications to the MediGuide Technology System (b)(4)

ATTACHMENTS TO SECTION 3

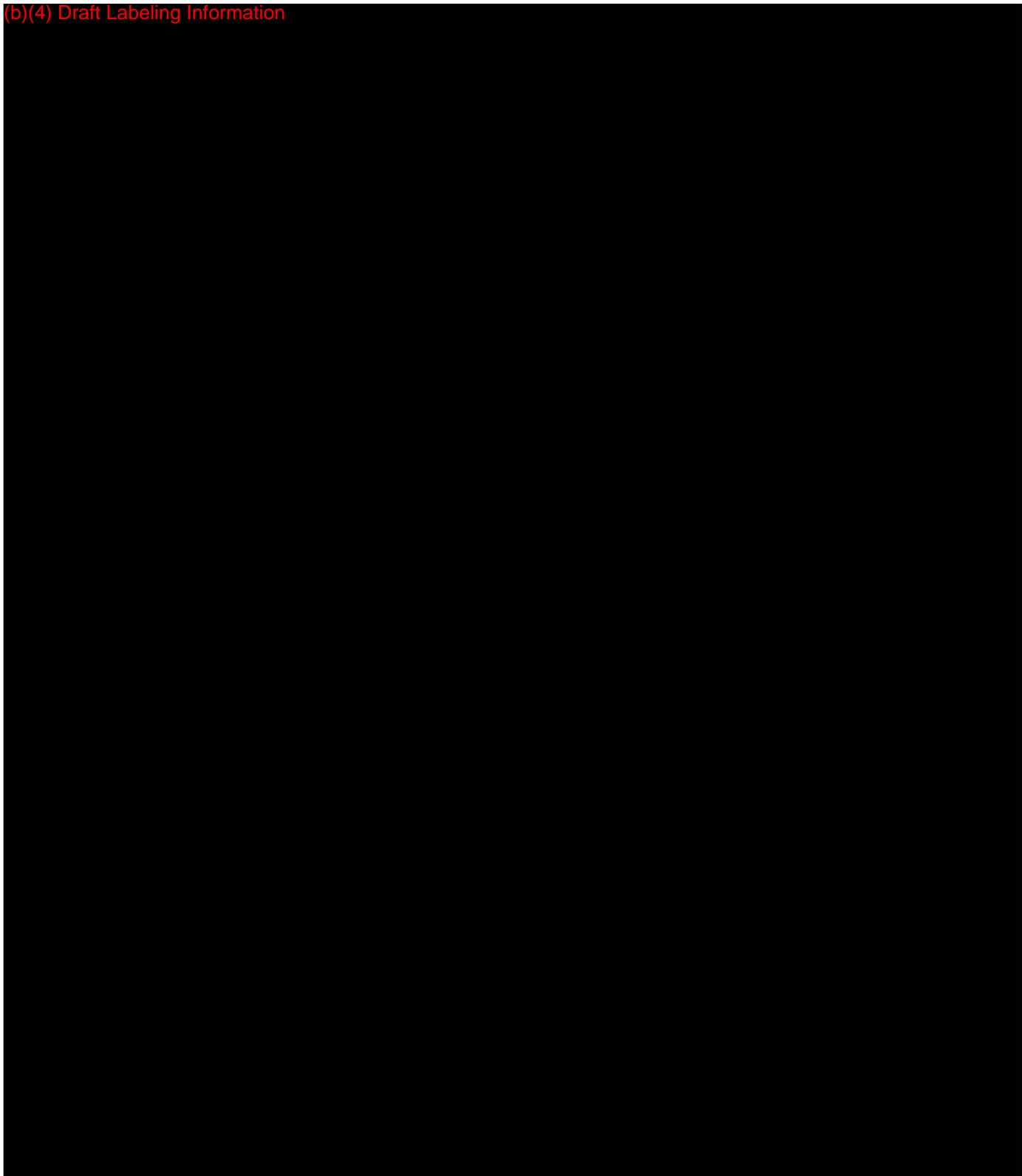
3-1 Substantial Equivalence Comparison Table

	Modified MediGuide Technology	Cleared MediGuide Technology (gMPS™ II)
510(k) Number	K _____	K102905
Product Code / Class	DQK / II	DQK / II
Regulation	Programmable diagnostic computer (870.1425)	Programmable diagnostic computer (870.1425)
Manufacturer	MediGuide Navigation Systems, St. Jude Medical	MediGuide (a St. Jude Medical company)
Intended Use and Indications for Use	The MediGuide Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide-enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.	The Guided Medical Positioning System (gMPS™ II) is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a gMPS™ enabled (equipped with a gMPS™ sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.
System Components	(b)(4)	
Applicable Procedures		
Navigation Technology		

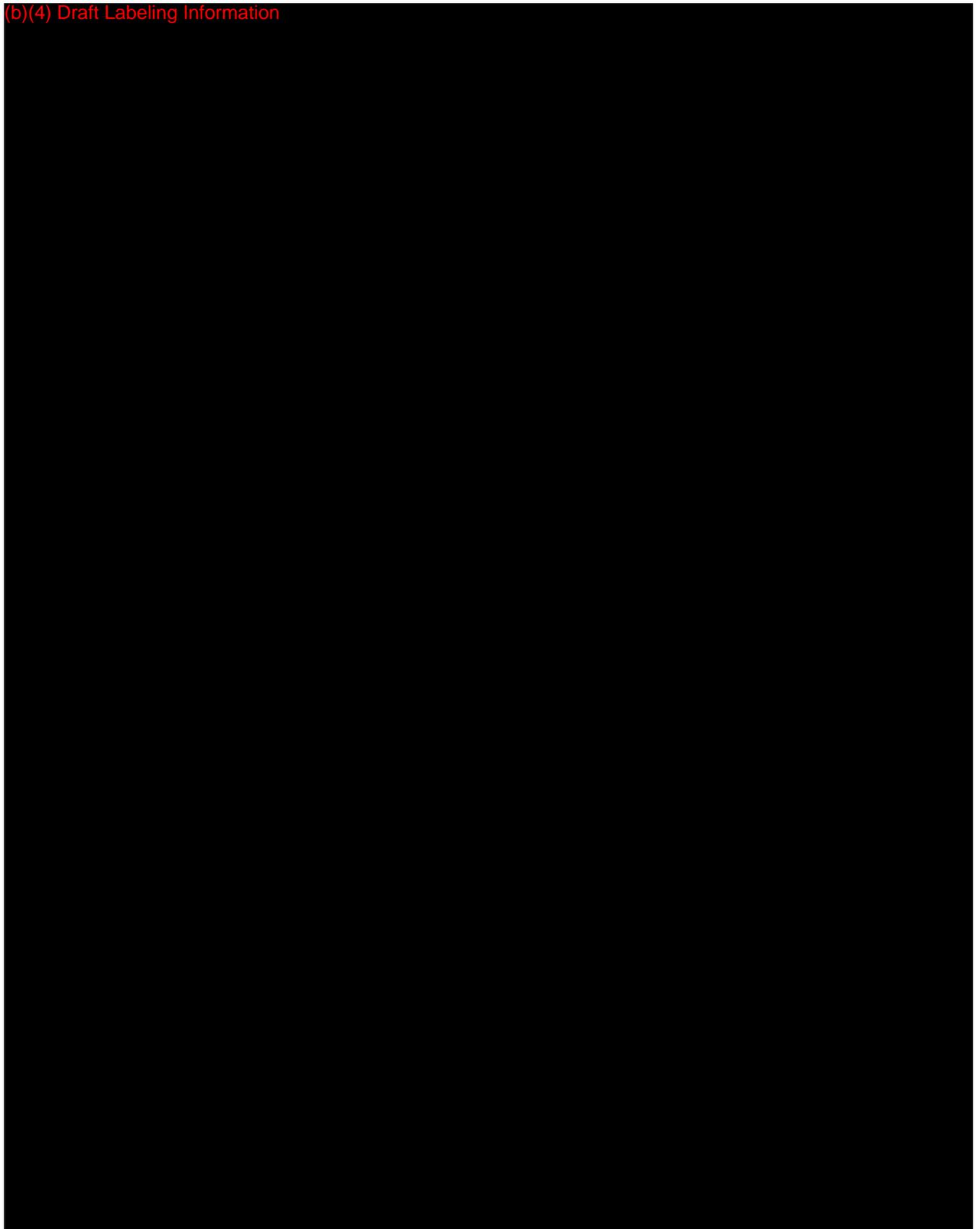
	Modified MediGuide Technology	Cleared MediGuide Technology (gMPS™ II)
Field Strength	(b)(4)	
Source of Magnetic Field		
Add On to Conventional Cathlab X-Ray		
Main Capabilities		

4 **PROPOSED LABELING FOR THE MODIFIED DEVICE**

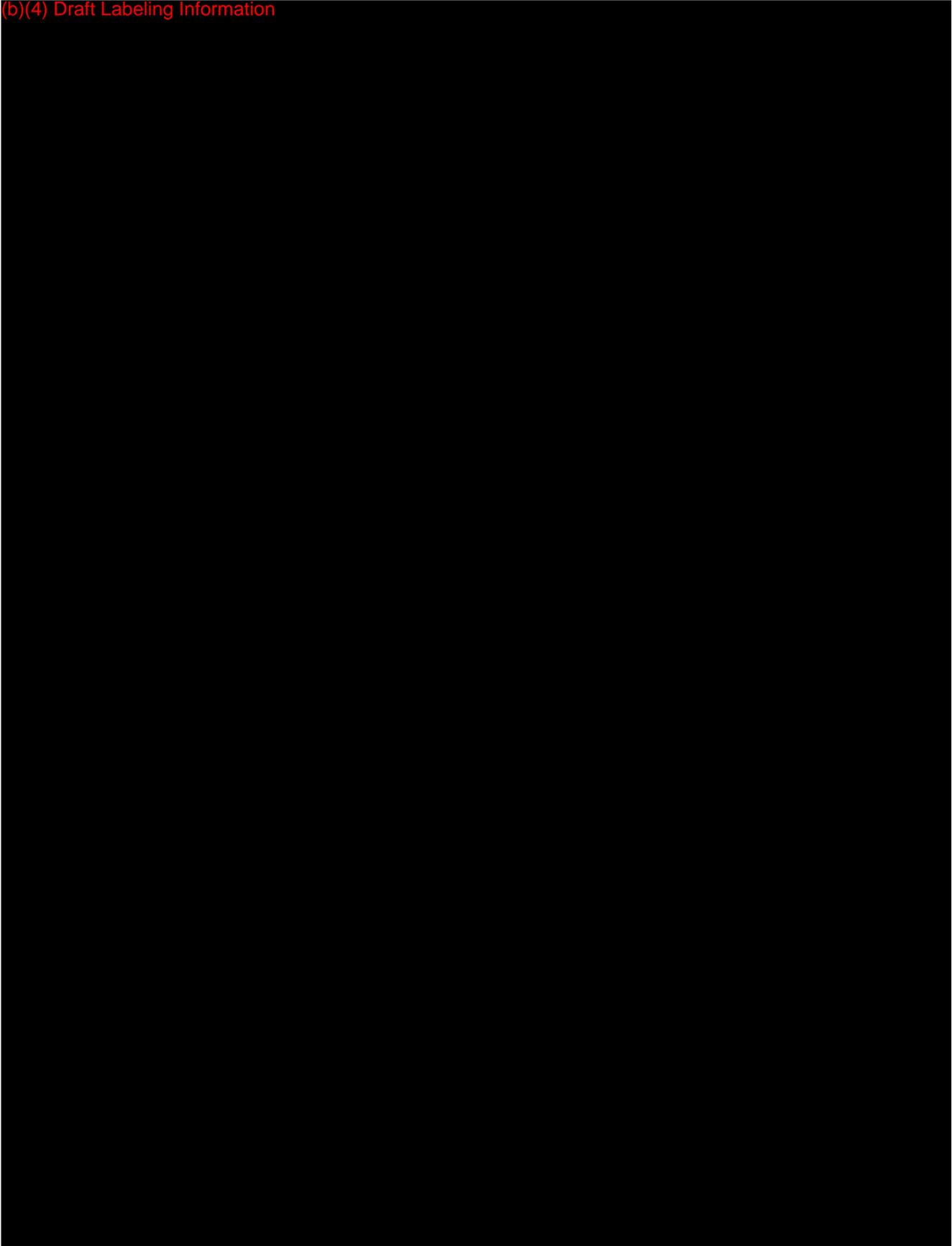
(b)(4) Draft Labeling Information



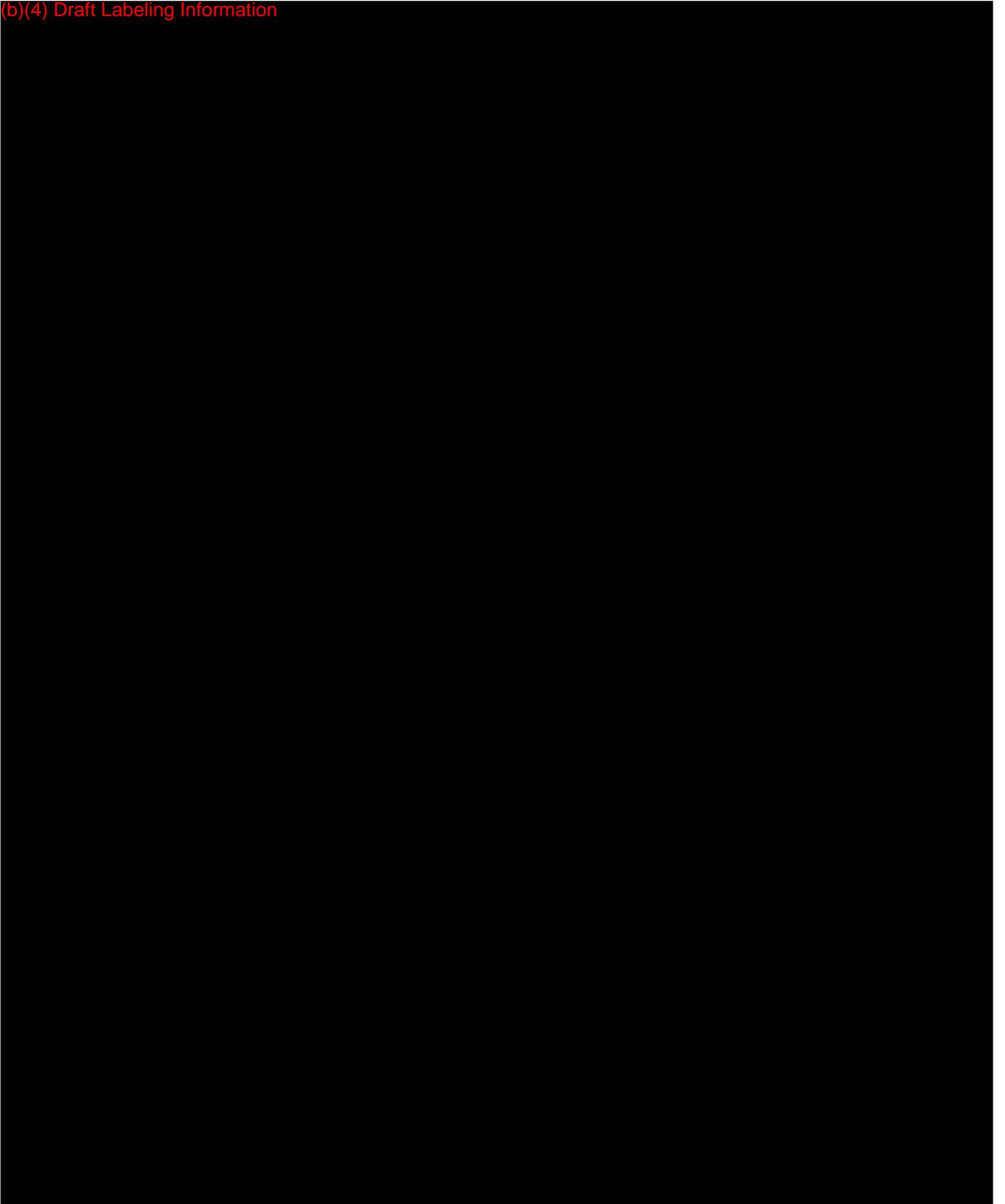
(b)(4) Draft Labeling Information



(b)(4) Draft Labeling Information



(b)(4) Draft Labeling Information



MediGuide Technology System Label (placed on the MediGuide Technology Console)

MediGuide™ Technology

Input Voltage Range	100 -240 VAC
Frequency	50 - 60 Hz
Current	4A -8A

R ONLY






GTIN: 0541473421883



(01)0541473421883(11)111019(21)0123456789

2011-10
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 📠 651-647-9464 / 800-374-2505
 afcustomerservice@sjm.com
 www.sjm.com



(91)100053540(92)MG1000

REF MG1000
SN 0123456789



**ETL CLASSIFIED
 CONFORMS TO
 UL STD 60601-1
 IEC STD 60601-1-1
 IEC STD 60601-1-4
 CERTIFIED TO
 CAN/CSA STD C22.2 NO. 601.1**

100053545 Ver B



ST. JUDE MEDICAL™
 MORE CONTROL. LESS RISK.

MediGuide Technology Console Label

2011-10
 St. Jude Medical
 One St. Jude Medical Drive
 St. Paul, Minnesota 55117 USA
 ☎ 651-756-6985 / 800-374-8038
 📠 651-647-9464 / 800-374-2505
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 www.sjm.com

MPSC
REF MB0755B-00
SN 0123456789







ST. JUDE MEDICAL™
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10005348 Ver A

MediGuide Technology Console Packaging Label

MPSC

GTIN: 0541473421877



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 **2011-10**

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(91)MB0755B-00(92)MB0755B-00



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ATTACHMENT TO SECTION 4

4-1 User's Manual for the Cardiac applications

ATTACHMENT 4-1

MediGuide Technology - User's Manual For Cardiac Applications

REVISION HISTORY				
REV	CHG NO	DESCRIPTION	DATE	APPROVED
(b)(4)		(b)(4)	3 Jan 2012	(b)(6)
(b)(4)		(b)(4)	22 Jan 2012	(b)(6)

DISTRIBUTION LIST		
COPY	NAME	TITLE / DEPARTMENT
(b)(4)	(b)(4)	Quality Assurance

PROGRAM NAME: GMPS

ALL SHEETS ARE THE SAME REVISION

FCTN	TITLE	NAME	SIGNATURE	DATE	ST. JUDE MEDICAL	St Jude Medical MediGuide Navigation Systems Advanced Technology Center P.O.B 15003, Haifa 31053, Israel
(b)(4)	Prod Dir	(b)(6)		30/1/21	 ST. JUDE MEDICAL <small>ADVANCED TECHNOLOGY CENTER</small>	MediGuide Technology User Manual
	Sys Dir			30/1/12		
	Prog Dir			30-1-12		
	QA Dir			30/Jan 2012		
					SIZE	DOC. NO.
					(b)(4)	(b)(4)
					SCALE NONE	SHEET 1 OF 95

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MediGuide Technology for Cardiac Applications

User's Manual

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Document no. (b)(4)
Revision (b)(4)



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DISCLAIMER

MediGuide Ltd. shall not be liable nor obligated in any manner in respect of bodily injury and/or property damage arising from the use of this manual if such use is not in strict compliance with instructions and safety precautions contained in the relevant operating manuals and in all supplements thereto, in all product labels, and according to all terms of warranty and sale of this system, nor if any change not authorized by **MediGuide Ltd.** is made to the system contained herein.

Manufacturer:

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One St. Jude Medical Drive
St. Paul, MN 55117USA

Tel: +1-651-7562000; Fax: 1-651-7563301.
WEB: www.sim.com

European Authorized Representative:

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Borkstrasse 10, 48163 Munster, Germany
Tel. +49-251322660
FAX +49-251322662





Preface

This User's Manual describes the operation of the MediGuide Technology, while working in conjunction with MediGuide Enabled™ devices. The Manual covers the use of the MediGuide Cardiac Applications.

Prior to use, read this entire document.



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1 Safety

The MediGuide™ System conforms to all safety standards and requirements as specified in Chapter 1 of this manual:

- ◆ Conventions (page 1-1)
- ◆ System Labels (page 1-2)
- ◆ Safety Guidelines (page 1-4)
- ◆ Data Safety (page 1-8)

1.1 Conventions

The safety instructions in this manual are for the protection of the patient, catheterization laboratory (cath lab) personnel and service personnel. They identify hazards that might occur if instructions are ignored. The identified hazards are defined and classified as follows:



WARNING indicates that PERSONAL INJURY OR DEATH might occur to patient and/or User, if the User does not observe the provided information.



CAUTION indicates that DAMAGE TO EQUIPMENT might occur if the User does not observe the provided information.

NOTE

NOTE indicates that INCONVENIENCE TO THE USER (such as loss of text entries) might result, if the User does not observe the provided information.

1.2 System Labels

The following symbols are used on the product or product packaging for the MediGuide™ System and any of its components:



This symbol indicates that the equipment on which it appears is intended for direct cardiac application (type CF), and includes circuitry to limit the patient leakage current to the levels specified in UL 2601-1 and EN 60601-1.



Voltage Hazard sign



Marks the internal functional earth terminal



Patient Connector BF sign



Non-sterile



Temperature Limitation



Fragile, handle with care



Keep Dry



Manufacturer



Catalog Number



Serial Number



"Dispose of hardware in accordance with local law"



Caution



Telephone



Facsimile



Warning



Authorized representative in the European Community



Consult Instructions for Use



Dangerous voltage



Notified body CE Mark

1.3 Safety Guidelines

1. Before use, carefully read this manual and the precautionary information. Follow the instructions in this manual while using the system.
2. This product was designed and manufactured to ensure maximum safety of operation. It should be operated and maintained in strict compliance with the safety precautions, warnings and operating instructions contained herein.
3. Inappropriate use of the System might lead to inaccurate information presented to the user, which may lead to patient injury. Please read this manual carefully and completely before attempting to use the system.
4. There are no user serviceable parts in this system. The product should be installed, maintained and serviced by qualified service personnel authorized by MediGuide Ltd.
5. The system in whole or in part should not be modified in any way by anyone, except by MediGuide Ltd. authorized personnel.
6. The minimum requirement for operating the system is the presence of authorized personnel.

7. It is important that this Manual be kept on hand and studied carefully by authorized users.
8. MediGuide Ltd. makes no representation, however, that the act of reading this manual renders the reader qualified to operate the system.
9. Unauthorized personnel should not be allowed access to the system.
10. If the product does not operate properly or if it fails to respond to the controls as described in this manual, the user should:
 - ◆ Ensure the safety of the patient and then the safety of the equipment
 - ◆ Follow the safety precautions as specified in this manual
 - ◆ Perform system shutdown
 - ◆ Contact a MediGuide's representative and report the incident.
11. The System utilizes one-patient use disposable sterile covers, for the following elements:
 - ◆ Table Side Unit (TSU – see Section 3.2.1 item 5) and Magnetic Transmitter Assembly (MTA – see Section 3.2.1 item 2).

These items might be contaminated and must be handled properly. The proper disposal of the sterile covers should be done according to the common practice of the Cath Lab, along with other Cath Lab disposable equipment.
12. The System should be used only for suitable patients as specified in MediGuide Enabled™ device instructions for use and as specified in the relevant sections included in Chapter 2 – System Description, of this manual.
13. The images/calculations provided by this system are intended as tools for the competent User. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.
14. Electrical Shock Hazard - do not remove or open system covers or plugs.
Internal circuits use high voltage capable of causing serious injury.

An electrical hazard might exist if any light, display or visual indicator stays on after the system is turned off. To prevent possible injury, turn the switch in the mains power supply box off and contact your service office immediately.

Fuses blown within 36 hours of being replaced might indicate malfunctioning electrical circuits within the system. Have the system checked by MediGuide's qualified service personnel. Do not attempt to replace any fuse.

15. Electrical Fire - conductive fluids that seep into the active circuit components of the system might cause short circuits that can result in electrical fires. Therefore, do not place any liquid or food on any part of the system.

To avoid electrical shocks or burns caused by the use of wrong type of fire extinguisher, make sure your fire extinguisher has been approved for use.

16. Explosion Hazard - do not operate the equipment in the presence of explosive liquids, vapors or gases. Do not plug in or turn the system on if hazardous substances are detected in the environment. If these substances are detected after the system has been turned on, do not attempt to turn off the unit or unplug it. Evacuate and ventilate the area before turning the system off.
17. Do not use the system if flammable anesthetics are present.
18. Overheating - DO NOT block the ventilation ports of the electronic equipment. Always maintain at least 12 cm (5 inches) clearance around the ventilation ports to prevent overheating and damage to the electronic hardware.
- If the temperature in the Magnetic Transmitters Assembly exceeds 80° C (176° F), the System will stop tracking, and a warning will be displayed on the System Display.
19. Anyone with implanted device other than the devices listed below, either personnel or patient, should not enter the room while the gMPS™ II is Powered ON.

The following devices are safe for use with gMPS™ II:

- i. St. Jude Medical Atlas II Cardiac Resynchronization Therapy (CRT) device
- ii. St. Jude Medical Affinity DR Pacemaker
- iii. St. Jude Medical Identity Pacemaker
- iv. St. Jude Medical Victory Pacemaker
- v. St. Jude Medical Current DR RF Implantable Cardioverter Defibrillator (ICD)

- vi. Medtronic EnPulse E2SR01 Pacemaker
 - vii. Medtronic Marquis VR 7230Cx ICD
20. Notwithstanding, patients with any implantable device might undergo the MediGuide procedure provided that the implantable device complies with ANSI/AAMI PC69 and the implantable device manufacturer's recommendations regarding the type of invasive procedure and exposure to electromagnetic interference (EMI) are strictly followed. In addition, it is recommended to turn off the magnetic field of the MediGuide Technology (as shown in Figure 4-4 and the note preceding it) during telemetry or communication between an external programmer and the implanted device, in case these are recommended by the implanted device manufacturer.
21. When the System is Powered ON, it is recommended to keep a minimum distance of 5 cm (2 inches) from the Magnetic Transmitters Assembly positioned on the X-ray Detector. However, a momentary approach to the X-Ray Detector is acceptable.

WARNING:

An X-ray hazard is present during live fluoroscopy.

- 22. Before starting the first MediGuide procedure, perform the daily tests specified in Section 4 - Using MediGuide.
- 23. The system continuously monitors its operation and displays status information on the System Displays. In case of malfunction, a corresponding warning will appear. Carefully watch the System Display for status information and warnings.
- 24. DO NOT bring items containing metallic elements closer than 20 cm from the transmitters. Contact a MediGuide authorized technician when introducing new/untested devices containing metallic elements in the cath lab.
- 25. The additional monitors in the technician's room (where applicable) should be powered from the system's isolation-transformer output.

26. Do not place the MediGuide Patient Reference Patch on skin sites with erythema, lesions and/or injuries. Do not use on patients with skin irritation from contact with the MediGuide Patient Reference Patch contact.
27. Do not operate the system in a room where air-conditioning is not available. Full performance of the system is guaranteed only when ambient temperature is 18°-28°C] (64°-82°F)].

1.4 Data Safety

1. **BEFORE** starting a new MediGuide procedure, verify that the correct patient identification information has been entered . MediGuide application allocates a unique procedure ID to each procedure.
2. When completed, always backup MediGuide procedure on removable media as instructed in Export a MediGuide Procedure to Removable Media on page 5-2. As a default, a procedure is automatically saved on the hard drive.
3. If the free space on the hard disk is less than 40 GB when the user attempts to start a new procedure, a corresponding warning will be displayed on the System display, and the procedure start-up will be disabled. To free hard disk space, refer to Delete MediGuide Procedures from the Hard Disk on page 5-4.
4. If the working memory (RAM) is less than 1 GB when the user attempts to start a new procedure, a warning will be displayed on the System display, and the procedure start-up will be disabled. Shutdown and restart the system as per Chapter 4 -Using MediGuide.

2 Definitions, Acronyms and Abbreviations

The following definitions, acronyms and abbreviations are used in this manual:

Cath Lab	- Catheter Laboratory
Cine	- A recorded fluoroscopy sequence used for playback
CRT	- Cardiac Resynchronization Therapy
CS	- Coronary Sinus



MediGuide Connect	- Electronics Box
ECG	- Electrocardiogram
EMI	- Electromagnetic Interference
GUI	- Graphic User Interface
MediGuide Cath Connect	- Interconnection Box
ICD	- Implantable Cardioverter Defibrillator
IVC	- Inferior Vena Cava
LA	- Left Atrium, Left Atrial
LV	- Left Ventricle, Left Ventricular
MB	- Motion Box
MPSC	- MediGuide Console
MTA	- Magnetic Transmitter Assembly
Os, OS	- Ostium
P&O	- Position and Orientation
MediGuide Patient Reference	- Patient Reference Sensor/Motion sensor
RA	- Right Atrium, Right Atrial
RAM	- Random Access Memory
ROI	- Region of Interest
RV	- Right Ventricle, Right Ventricular
SVC	- Superior Vena Cava
(the) System	- The combined hardware and software comprising the MediGuide Technology and its application
TSU	- Table-Side Unit

3 System Description

This chapter describes the MediGuide™ System, in the following breakdown:

- ◆ Intended Use on page 3-10
- ◆ Physical Structure on page 3-10
- ◆ System Functionalities on page 3-14
- ◆ System Limitations on page 3-22
- ◆ System Specifications on page 3-23
- ◆ User Interface and Operating Controls on page 3-25

3.1 Intended Use

The MediGuide™ System is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real-time tip positioning and navigation of MediGuide Enabled™ (equipped with a MediGuide sensor) diagnostic or therapeutic invasive devices used in vascular or cardiac interventions in the cath lab environment, on both live fluoroscopy or recorded background. The system is indicated for use as an adjunct to fluoroscopy.

3.2 Physical Structure

3.2.1 The System

The MediGuide™ System consists of the following hardware units (see Figure 3-1 below):

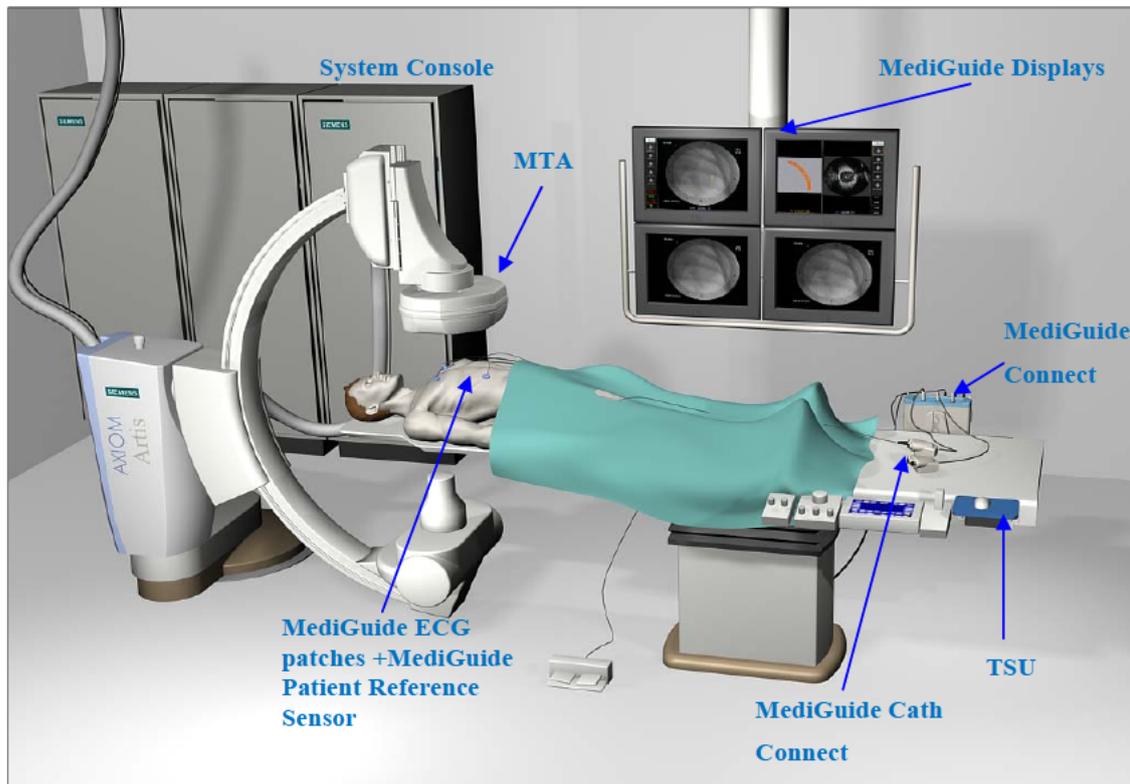


Figure 3-1: Room Layout of the MediGuide System

1. System Console (MPSC) – consists of the System computing and communications units.

CAUTION:



In order to assure adequate performance, it is crucial to verify that the MPSC ventilation ports are not blocked. Blocking the ventilation ports may result in system overheating and shutdown

Do not place any liquid materials or crumbing-potential items in the vicinity of the MPSC.

2. Magnetic Transmitter Assembly (MTA) – assembled on the X-Ray Detector. It generates a controlled magnetic field above the patient chest.
3. MediGuide Cath Connect – an electronic interface between the MediGuide Connect and the MediGuide Enabled™ device. The MediGuide Cath Connect is placed on the end of the patient table. When in use, the MediGuide Enabled™ device is connected to the MediGuide Cath Connect.

CAUTION:



All table side units and especially the MediGuide Cath Connect should be situated at least 28 inches (70 cm) away from the MTA. Placing the units in close vicinity to the MTA might lead to inaccurate tracking.

Note:

Between procedures, the MediGuide Cath Connect should be stored next to or beneath the patient table to avoid disturbance to other operations.

4. Electronic Box (MediGuide Connect) - used to connect the Patient Reference Sensor, the MediGuide Cath Connect and MediGuide ECG leads to the MediGuide Console. The MediGuide Connect is attached to the table patient rails on the left side of the patient table (opposite the operators), or installed beneath the patient table.
5. Table Side Unit (TSU) - a standard mouse and slide surface, through which the User operates the system. The TSU is attached to the patient table rails, on the right side of the table. In addition, it consists of the Power ON/OFF main switch of the System.

CAUTION:



Do not place any liquid materials or crumbing-potential items near the MediGuide Connect, MediGuide Cath Connect, or the TSU.

In order to avoid system over-heating, it is important to verify that all units attached to the patient table (MediGuide Connect/MediGuide Cath Connect/TSU) shall have proper heat convection when not being used in a procedure.

Note:

All cables of the units attached to the patient table (MediGuide Connect/MediGuide Cath Connect/TSU) should be handled orderly and tidy, in order to prevent cable nits, which might result with a cable functionality problem.

6. Output Display – the MediGuide Technology output is displayed in the Cath Lab and may also be displayed in the Technician room (if a Technician Interface Station is installed). The output display includes the X-Ray images as well as the superimposed MediGuide visualization information (e.g., device tracking and landmark positioning), and it covers two screens. The left screen, named Primary Display, displays superimposed device or landmark

P&O data onto 2D X-Ray images, either live (currently acquired) or previously recorded, according to the projection direction of each image. In addition, the system controls reside on the Primary Display. The right screen, named Secondary Display, displays by default an interactive 3D display of the tracked MediGuide-enabled devices and landmarks. This interactive view can be freely rotated by the user, since it is not projected on fluoroscopy where the viewing angle is dictated. The MediGuide Technology is supplied with two monitors to be installed in the technician room (in case a Technician Interface Station is installed), while the Cath Lab display is executed by a MediGuide technician in accordance with the configuration of each Cath Lab, which is not supplied by MediGuide. Two Cath Lab display options are currently enabled: (1) two commercially available high resolution color monitors dedicated to the MediGuide Technology output display; (2) a large display that emulates several monitors and can dedicate two monitors to the MediGuide Technology output. In both options the monitors should comply with the MediGuide Technology specifications for display and monitor.

7. MediGuide Patient Reference – used as a reference sensor to compensate the calculated positioning of the MediGuide Enabled™ device for patient motions and to sense respiration motions. The proximal end of the MediGuide Patient Reference (the connector) is connected to the MediGuide Connect. The distal end (the sensor) is externally attached to the patient chest at a predefined position via the MediGuide Patient Reference Patch. MediGuide Patient Reference is also addressed as ‘Motion Sensor’ on the user interface.
8. MediGuide ECG – a dedicated three-lead ECG recorder used to synchronize between all signals (the X-ray images, the P&O signal and MediGuide generated 3D objects) and the patient cardiac cycle. The ECG cable is connected to the Electronic Box and the three leads are attached to the patient’s chest at a predefined location via regular off-the-shelf ECG electrodes.

9. Technician Interface Station (optional) - located outside the catheterization laboratory. It includes two monitors, which replicate the system displays, a keyboard and a mouse. The Technician Interface Station is used for typing in alpha-numeric patient data and for maintenance purposes (backup/restore MediGuide procedures to/from removable media and delete MediGuide procedures from the hard drive).
10. MediGuide Enabled™ device – a single-use, sterilized device with a magnetic P&O sensor located at a known position. The proximal end of the device is connected to the MediGuide Cath Connect (up to 3 devices simultaneously in each MediGuide Cath Connect).

3.2.2 MediGuide-Enabled Devices

The MediGuide Enabled™ devices are equipped with miniaturized MediGuide sensors, allowing their position and orientation (P&O) to be tracked.

The MediGuide sensors are electrically connected through electric cables threaded along the device body, extended proximally to the hub and terminated by electric connectors.

When located in the Motion Box during System operation, electric voltage is induced on the MediGuide sensor, which is measured by the System console via the electric cable and connector to the MediGuide Cath Connect, for the calculation of the sensor's P&O.

3.3 System Functionalities

3.3.1 Overview

The System consists of hardware and software elements, which are installed in conjunction with the existing X-ray Imaging System in a cath lab. The X-ray Imaging System, equipped with the System elements, continues to perform safely and effectively per its intended use as fluoroscopic imaging, while enabling device tracking and enhanced visualization tools supplied by MediGuide capabilities.

The navigation/tracking data is acquired by MediGuide Enabled™ devices, which are invasive devices equipped with miniaturized MediGuide sensors. When the MediGuide sensor is located in a controlled environment with a low intensity magnetic field (less than 200 μ Tesla nominal value) generated by the system, its real-time three-dimensional position and orientation are calculated and displayed .

The System, in conjunction with conventional X-ray fluoroscopy, is intended to provide the following capabilities:

- Track the P&Oof MediGuideEnabled™ devices that are within the Motion Box (MB), a volume around the relevant anatomical structure of the patient where the System generates low intensity magnetic field. The system can track up to three devices simultaneously.
- Continuously display the MediGuide Enabled™ device position on Live fluoroscopy images
- Continuously display the MediGuide Enabled™ device position on cine playback
- Allow landmark assignment at points of interest in the inspected anatomy, and displaying these landmarks on live fluoroscopy and cine playback

3.3.2 Magnetic System's Positioning and Navigation Principle

The MediGuide Technology positioning system is based on capturing and processing the signals received from magnetic sensors upon the activation of a controlled low AC magnetic field (less than 200 μ Tesla nominal value). The magnetic transmitters (MTA) generate the magnetic field around the relevant patient's anatomical structure, in a defined 3D space, called the Motion Box (MB).

Note: Due to the fact that the MTA emits a magnetic field, it is recommended to keep at least 15cm (6") away from the MTA while the system is operated.

When a MediGuide sensor is located in the MB, it senses the magnetic field and the system can calculate its real-time position and orientation (P&O). This concept is illustrated in Figure 3-2 below.

When a sensor moves outside the Motion Box, its calculated P&O becomes invalid and the user is notified.

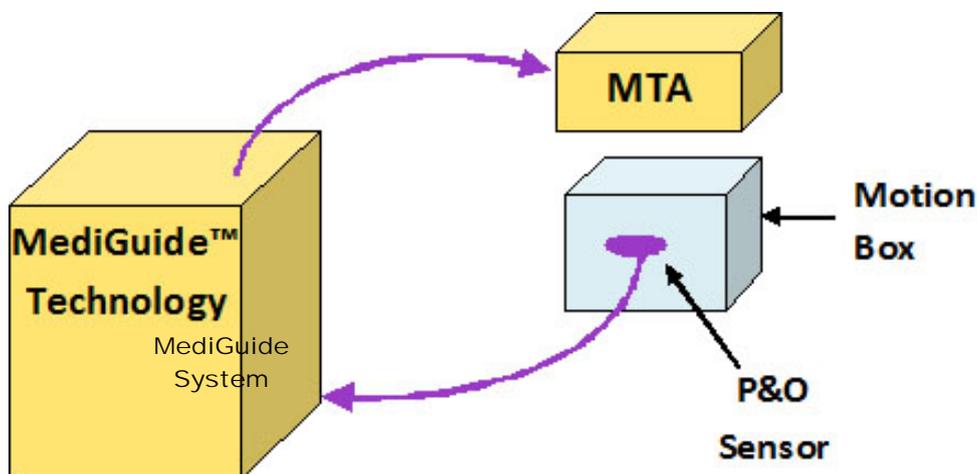


Figure 3-2: Magnetic Tracking System Concept

3.3.3 Projection on Live Fluoroscopy

The System is capable of tracking any MediGuide Enabled™ device on live fluoroscopic images. This feature uses calibration between the MB volume and the X-ray image. As a result, the P&O of any tracked MediGuide sensor can be projected on live X-ray images. Depending on the context, both position and orientation, or just position of the device is displayed.

3.3.4 Tracking on Images Acquired from Different Angulations

In addition to the MediGuide sensor, the System uses the MediGuide Patient Reference for correlation of the patient's position and orientation relative to the transmitters. As a result, the current P&O of any MediGuide Enabled device™ can be projected on a previous X-ray image, even if taken from different C-arm angulations. The transformation between the current and previous angulations of the C-arm is performed using the MediGuide Patient Reference's P&O as an anchor.

3.3.5 Motion Compensation

The System includes a motion compensation function, handling the following motion components:

- a) Motion of the patient with respect to the X-ray imager (as discussed in Paragraph 3.3.4), due to motion of the C-arm, the operating table or the patient's body. This compensation is performed by using the P&O of the MediGuide Patient Reference Sensor positioned on the relevant part of the patient's body and correlates between the patient and the System transmitters. Therefore, registration of the MediGuide tracking with the X-ray image is kept.
- b) Motion of the patient's heart with respect to the patient's body due to the cardiac pulsation. This compensation is performed by correlation of the motion of a MediGuide Enabled™ device with real-time cardiac phase computed from the ECG signal.
- c) Motion of the patient's heart due to respiration. This compensation is performed by correlation of the motion of a MediGuide Enabled™ device with a respiration signal computed from the motion of the MediGuide Patient Reference. The respiratory compensation is also cross-correlated with the cardiac compensation, due to the complex relationships between these two motion components.

3.3.6 Tracking on Previously-Acquired Cine

The combined effect of the principles and features described in Paragraphs 3.3.1-3.3.5 is the ability of the System to track a MediGuide Enabled™ device on previously-acquired X-ray images. To project the current position and orientation of an enabled device on a previously-acquired image, the system computes the required compensation function between current P&O (with the current cardiac phase, current respiration status, and current patient position relative to the X-ray imager) and the position and orientation of the volume surrounding the device at the time when the selected X-ray image was acquired (with its corresponding cardiac phase, respiration status, and patient position relative to the X-ray imager).

The System enables real-time tracking of a MediGuide Enabled™ device on previously-acquired fluoroscopy images. A common mode of operation can, therefore, be using a pre-acquired cine-loop as a roadmap on which the MediGuide Enabled™ devices are tracked, in addition to using live fluoroscopy .

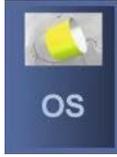
3.3.7 Landmarks

The System enables the user to place and visualize landmarks based on the System sensors' P&O data. The landmarks can be tracked on live and previously-acquired X-ray images, similarly to the System device tracking.

The following landmarks can be assigned when using the MediGuide Cardiac Applications:

Landmark	Acronym	Graphics	Cardiac Navigation Application	Cardiac Navigation with Angio Survey™ Application
Superior Vena Cava	SVC		√	√
Inferior Vena Cava	IVC		√	√
Coronary Sinus Ostium	CS OS		√	√
Coronary Sinus Reference	CS Ref			√

Coronary Sinus Parking Position	CS Park		√	
Tricuspid Valve	TCV			√
Point Mark	Point Mark		√	√
Right Ventricular Outbound Tract	RVOT		√	
Right Atrial Appendage	RAA		√	
Right Inferior Pulmonary Vein Ostium	RIPV Ostium		√	
Right Superior Pulmonary Vein Ostium	RSPV Ostium		√	
Left Inferior Pulmonary Vein Ostium	LIPV Ostium		√	

Left Superior Pulmonary Vein Ostium	LSPV Ostium		√	
Fossa Ovalis (Ostium)	OS		√	

3.3.8 Catheter Shaft Rendering

Note: This feature is only available for the Cardiac Navigation with Angio Survey™ Application

The MediGuide Technology features an option to display an approximation of the shaft of a MediGuide Enabled™ device (for example, outer guide catheter). The approximated shaft is displayed between a pre-defined landmark and the tip of the MediGuide Enabled device, as seen in Figure 3-3. The purpose is to show how the device’s shaft behaves, in addition to the tip which is tracked by the system. This may be useful, for example, when an outer guide catheter is manipulated in the right atrium during CS cannulation. It should be noted that the rendered shaft is only an approximation, and not necessarily an accurate representation of the catheter.



Figure 3-3: Shaft Rendering

3.3.9 Angio Survey™ 2D Fusion

Note: This feature is only available for the Cardiac Navigation with Angio Survey™ Application

The MediGuide Technology features an option to display live fluoroscopy with a fused transparent overlay of a matching pre-recorded fluoroscopy, as seen in Figure 3-4. The purpose of this feature is to display a previously imaged anatomy (e.g., a venogram of the CS) while using live fluoroscopy. This enables the user to visualize the tools and devices with respect to the anatomy.

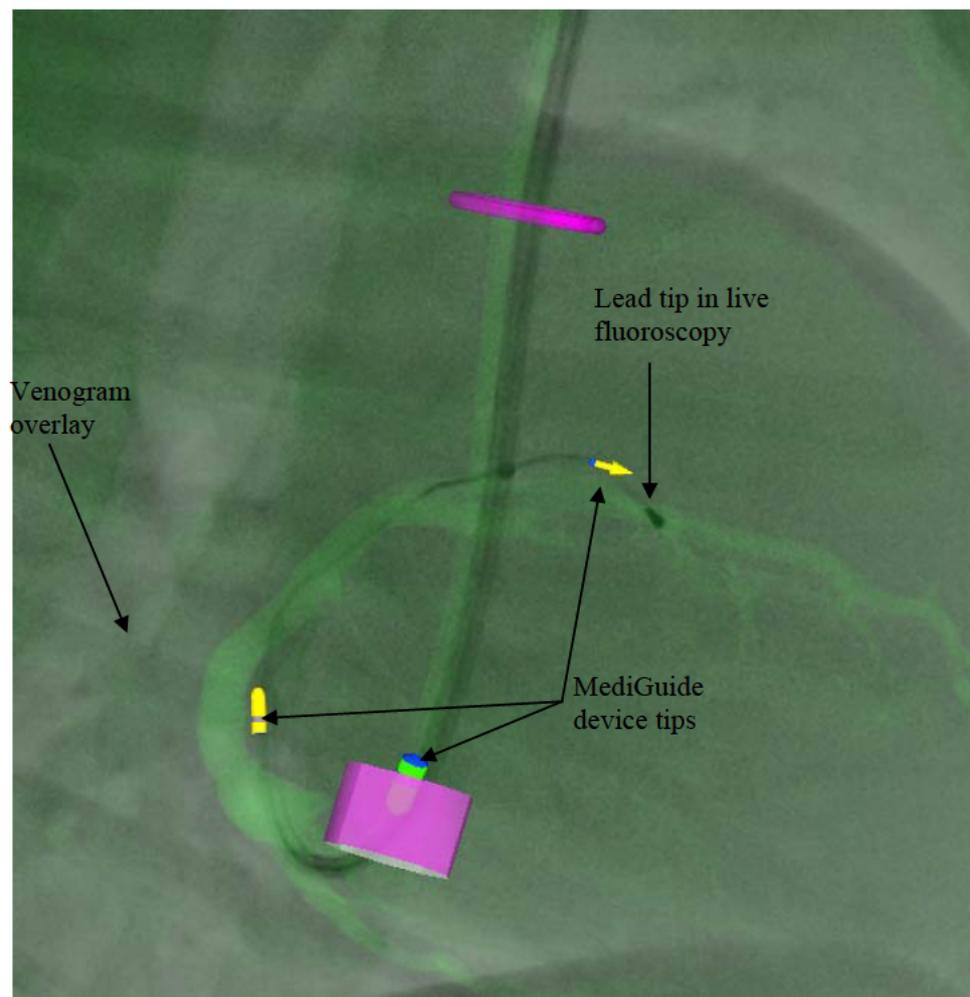


Figure 3-4: Angio Survey™ 2D Fusion

3.3.10 Angio Survey™ 3D

Note: This feature is only available for the Cardiac Navigation with Angio Survey™ Application

The MediGuide Technology features a capability to reconstruct a 3D model of a vascular anatomical structure from two cine-loops where contrast agent is used, recorded at different projections. The reconstructed model can be displayed in 3D and projected on live and pre-recorded fluoroscopy, as seen in Figure 3-5.

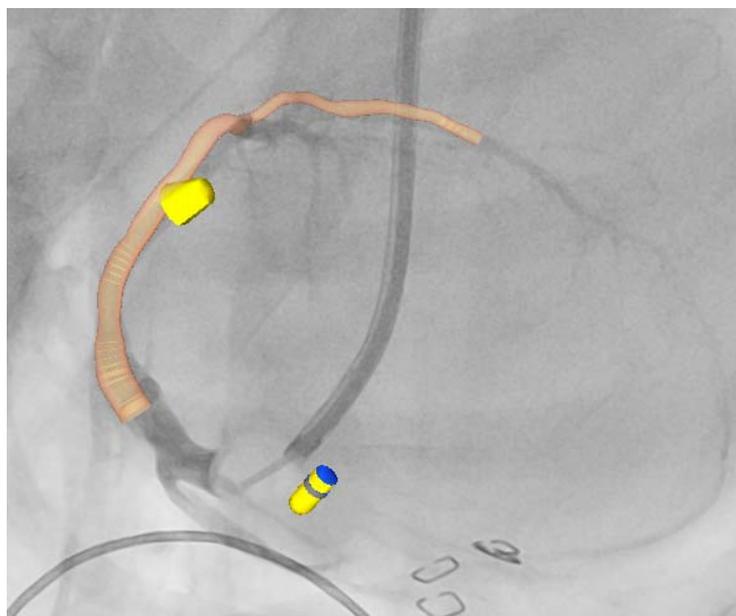


Figure 3-5: Angio Survey™ 3D

3.3.11 Third-party Data Export

Note: This feature is only available for the Cardiac Navigation Application

MediGuide™ Technology possesses a data channel that enables 3rd-party systems to receive real time MediGuide™ Technology tracking data of all the active MediGuide™ Technology Sensors, including the PRS. To use this interface, please contact St. Jude Medical for support.

3.4 System Limitations

Due to the MediGuide magnetic field characteristics, the following limitations apply to the X-ray system operation during MediGuide procedures:

X-ray detector Up/Down movement is limited to 10 inches (24 cm), due to magnetic interference of the detector metal base.

The distance between the X-ray detector and the patient body should not exceed 15 cm (6 inches), due to Motion Box dimensions.

The C-Arm rotation angle from home position is limited as follows:

LAO-RAO axis to $\pm 60^\circ$

CAU-CRA axis to $\pm 45^\circ$

Rotation angle axis to $\pm 6^\circ$

3.4.1 MediGuide Compatible X-ray Imaging Systems

The System is designed to work in conjunction with an X-ray System. Currently, the System is compatible to work with the following X-ray systems, under the detailed limitations:

Siemens AXIOM Artis dFC and AXIOM Artis Zee under the following limitations:

- ◆ System Frame Rate: Fluoro – 7.5-30 [fps] ; Cine – 7.5-30[fps]
- ◆ The System is automatically synchronized to X-ray System Detector Zoom.
- ◆ X-Ray exam set is set to a dedicated "gMPS" exam set. On other cases, the System is disabled.
- ◆ Bi-Plane mode is not supported. Whenever "Bi-Plane" is activated, the system stops transmissions, and resume functionality when "Bi-Plane" mode is turned off.

3.4.2 MediGuide interference with other systems

When introducing a new system/device which resides by MediGuide units, contact a MediGuide authorized technician, in order to verify that no interference occurs.

3.5 System Specifications

This section provides the electrical, magnetic, display, physical, and environmental specifications of the System.

For the MediGuide Enabled™ device Specifications, refer to the MediGuide Enabled™ device Instructions for Use packaged with the MediGuide Enabled™ device.

Type	Parameter	Value
Electrical	Input Power	110-240 VAC 50-60Hz
	Max Input Current	10 A @ 110 V AC 4.5 A @ 240 V AC
	Max Power Consumption	1KW
	Patient Isolation	The unit is classified as Class I system continuously operated, ordinary equipment with type BF and CF applied parts. Patient leakage current is limited to the levels specified in IEC-EN-UL 60601-1, 60601-1-1
Magnetic Field	Nominal Patient Magnetic Field Flux	<200 μ T @ audio frequency
	Nominal Personnel Magnetic Field Flux	<10 μ T @ audio frequencies
	Minimal Motion Box Dimensions	340 mm x 280 mm x 200 mm (W x H x D)
Electric Field	Patient Electric Field	<420 V/m @ audio frequencies
	Personnel Electric Field	<30 V/m max @ audio frequencies
Display	Resolution	1280 x 1024
Physical		



Type	Parameter	Value
Console	Dimensions	80 cm x 199 cm x 44 cm (W x H x D)
	Weight	200 Kg max
Monitor (each)	Dimensions	19"
	Weight	15 lbs. (6 kg)
Environmental conditions (transport and storage)	Ambient Temperature	13°F (-25°C) through +158°F (+70°C)
	Relative Humidity	10% through 90%
	Atmospheric Pressure	500 hPa through 1060 hPa
Environmental conditions (operating)	Ambient Temperature	+50 °F (+10 °C) through +104 °F (+40 °C)
	Relative Humidity	30% through 75%
	Atmospheric Pressure	700 hPa through 1060 hPa

3.6 User Interface and Operating Controls

The following paragraphs describe the system operation using the software graphic user interface and hardware operating controls.

3.6.1 Operating Controls

The System is operated via a Graphic User Interface and Physical Controls, as follows:

Application Controls/Software User Interface Components:

- ◆ Graphic User Interface (GUI), which appears on the two system displays. The Primary Display (on the left) displays the Live fluoroscopy images and Cine-loops and the Secondary Display (on the right) displays status information and MediGuide objects in a 3D space or a dual cine view (as selected by the user). The GUI consists of display windows, menus, buttons and sliders. In addition, it displays system warnings, measurements, status information, and other system messages.
- ◆ Table Side Unit (TSU), which functions as a point and select device, used by the physician to operate the GUI during a clinical procedure. For a detailed description refer to Section 3.6.2 below.
- ◆ (Optional) Technician Interface Station, which in addition to replicating the system displays, includes a keyboard for entering alphanumeric data.

Hardware Controls:

The X-ray machine Fluoroscopy and Cine-loop Pedals are located on the floor next to the physician. These pedals are used to Start/Stop fluoroscopy and Cine-loop recording, respectively. These pedals are not part of the MediGuide System. See Figure 3-1 above for location of the pedals.

3.6.2 Table Side Unit

The Table Side Unit (TSU) is shown in figure 3-6 below. The TSU is used by the user to select a menu item or activate a button on the System GUI, or to manipulate a displayed 2D image or the 3D display on the Secondary Display.



Figure 3-6. Table Side Unit

To select a specific GUI element:

- ◆ While watching the System displays, move the mouse so that the mouse pointer will be placed over the desired GUI element (menu item or button)
- ◆ Press the <Left> mouse button. The operation corresponding to the selected GUI element will be performed.

Note: Instructions to select a GUI element will be phrased as “Select element name”, where element name refers to actual menu entry or button to be selected or activated.

The display of 2D images and 3D objects can be manipulated via the mouse, as follows:

To zoom a 2D image or 3D display in or out:

Place the mouse cursor over the relevant display, right-click and drag the cursor up (to zoom in) or down (to zoom out) to the desired zoom.

To pan a 2D image or 3D display:

Move the mouse cursor over the relevant display, middle-click and drag the cursor to the desired location

To rotate the 3D display:

Move the mouse cursor over the 3D display, left-click and drag the cursor in the desired directions.

4 Using MediGuide Application

4.1 Conventions

The following Conventions are used when describing the interaction with the System:

- ◆ Hardware System Parts are stated in initial caps: Patient Reference Sensor
- ◆ System modes are stated in initial caps in bold faced characters: **System Mode**
- ◆ Menu entries, dialog and control names are specified in bold faced characters within the following parenthesis: {**System**} menu entry
- ◆ Hardware controls (such as buttons, levers, and switches) are indicated in bold faced characters within the following parenthesis: <**Power ON**>
- ◆ Software buttons are indicated in bold faced characters within the following parenthesis: [**OK**]
- ◆ Operations where special care should be taken are given in capital and bold letters

4.2 System Start-up and Shutdown

It is recommended to start-up the System once, at the beginning of the day, and to shut it down at the end of the last MediGuide procedure.

4.2.1 System Start-up

System start-up consists of two steps:

1. System Power-Up.
2. Start-Up Verification Procedure.

4.2.1.1 System Power-Up

1. Press the <Power Switch> button located on the TSU. See Figure 4-1 below.



Figure 4-1: TSU with main ON/OFF Switch

Log in and select the desired application from the MediGuide Technology screen (see Figure 4-2). The startup screen is displayed on the System displays (see Figure 4-3).



Figure 4-2: Application Shell screen



Figure 4-3: Startup Screen



CAUTION: The input / output ports of the Console are intended only to be used with MediGuide compatible equipment. Using the ports with incompatible equipment might result in system damage.

NOTE: If the system was shut down immediately prior to a power-up, wait at least 1 minute before powering-up again

NOTE: If at any time during the System operation there is a need to turn the magnetic field off, select the Turn Magnet Off button on the primary display (See Figure 4-4)

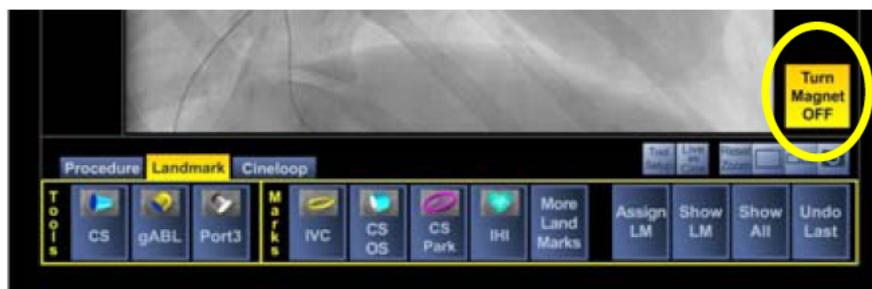


Figure 4-4: Turn Magnets Off Button

4.2.1.2 Start-up Verification Procedure ("Morning Test")

The Morning Test should be performed by a qualified user each day at start-up.

1. Verify that all detachable units (MediGuide Connect, MediGuide Cath Connect, System Displays) are connected to the System Console. Connect the MediGuide Patient Reference (Motion Sensor) to the MediGuide

Connect. Verify that MediGuide ECG device is connected to the MediGuide Connect.

2. Start a new MediGuide procedure, using "Morning Test" as patient name.
3. From the Tools Setup dialog box, select the PRS number that matches the one used (see Figure 4-5).

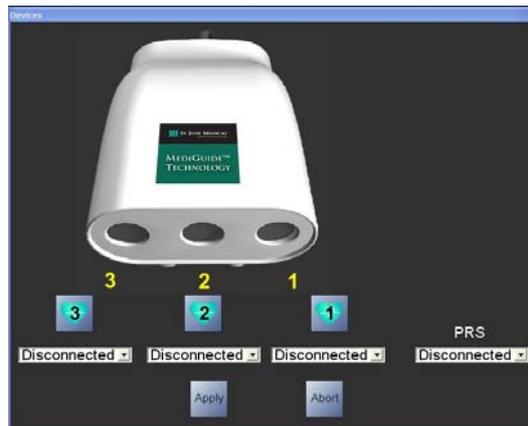


Figure 4-5: Selecting PRS number



Figure 4-6: Motion Sensor Valid Status

4. Verify magnetic system functionality:
 - ◆ Hold the Patient Reference Sensor inside the Motion Box and verify Valid reading in the status area as shown in Figure 4-6.
 - ◆ Hold the Patient Reference Sensor outside the Motion Box and verify appearance of the Out of MB indication in the status area.
5. Verify the Pedal functionality:
 - ◆ Place a non-metal object , such as a syringe, plastic bowl, etc., on the patient table.
 - ◆ Press down on the fluoroscopy pedal to verify imaging of the object on the 2D MediGuide Display.
6. Verify MediGuide Cath Connect functionality:
 - ◆ Attach the test device to the MediGuide Cath Connect.

WARNING: The test device, provided with the system, is a MediGuide Enabled™ device used for test purposes only. It is not intended to be used on human subjects. Using the test device on a human subject may result in injury.



- ◆ Hold the test device inside the Motion Box and verify that the Device field value shows Valid in the Status Area on the Secondary Display.
- ◆ Hold the test device outside of Motion Box and verify that the Device field value shows Invalid.
- ◆ Repeat this test for all three MediGuide Cath Connect ports.

7. Close the **Morning Test** procedure.

4.2.2 System Shutdown

To shutdown the System

1. Select the [Exit] button in application.

Note: Pressing the <Power Switch> for more than 10 seconds will result in an instant and complete hardware shutdown.

2. A confirmation window is displayed.
3. Select **[YES]** to Exit the application, or select **[NO]** to return to the System Mode. If **[YES]** is selected, the application will exit to the MediGuide Technology shell screen (see Figure 4-2).
4. Select the **Power Off**  button on the MediGuide Technology screen to shut the system down.

CAUTION: If, for any reason, abnormal software shutdown happens (such as in a software crash), it must be followed by turning OFF the power switch on the System Console and then turning it ON again to restart the system. Failure to turn the system OFF and ON following an abnormal shutdown may result in abnormal functionality .



5. Disconnect the MediGuide Patient Reference from the MediGuide Connect and return it to the box.
6. Carefully store the ECG leads and the MediGuide Cath Connect until the next MediGuide procedure.

4.3 Preparations for a New Procedure

The MediGuide procedure is intended to be performed during routine procedures for diagnosis and treatment. The preparation instructions provided in this chapter should be performed **before** the initiation of the planned procedure and **before** the MediGuide procedure.

Perform the following steps to prepare for a new MediGuide procedure:

1. Turn the System ON.

Note: Turn the system on before, or at the beginning of patient preparation to allow time for the system to warm up.

2. Prepare the patient according to clinical procedure characteristics
3. Connect the MediGuide Patient Reference and MediGuide ECG leads (see Sections 4.3.1 and 4.3.2, respectively).
4. Initiate a new MediGuide Procedure.
5. Prepare the MediGuide Cath Connect (See Section 4.3.3 below).
6. Prepare the MediGuide Enabled Devices and connect them to the MediGuide Cath Connect (See Section 4.3.3 below).

WARNING:



Do not attempt to connect a MediGuide™ Enabled device to the MediGuide Connect. Using a MediGuide Enabled™ device connected to the MediGuide Connect may result in electric shock to the patient.

7. Introduce the MediGuide Enabled™ devices and perform the clinical procedure.

Note: MediGuide Enabled™ devices (up to three devices concomitantly) may be connected, disconnected and re-connected at any time during the procedure.

Note: Before starting a new procedure, verify that no metal objects are present in the MTA vicinity (closer than 20cm) and the Motion box (closer than 10cm).

4.3.1 MediGuide Patient Reference attachment

The MediGuide Patient Reference should be connected to the MediGuide Connect at the “MediGuide Patient Reference 2” port as shown in Figure 4-7.

Note: To connect the MediGuide Patient Reference to the MediGuide Connect, lift the cover over the MediGuide Patient Reference connection ports, connect the MediGuide Patient Reference, then return the cover to the closed position (see Figure 4-7).

Connecting the MediGuide Patient Reference to a MediGuide Connect port other than “MediGuide Patient Reference 2” may yield erroneous system performance.

1. Verify that the MediGuide Patient Reference connector is securely connected at the MediGuide Connect port.
2. Attach the MediGuide Patient Reference to the MediGuide Patient Reference patch as shown in Figure 4-8.

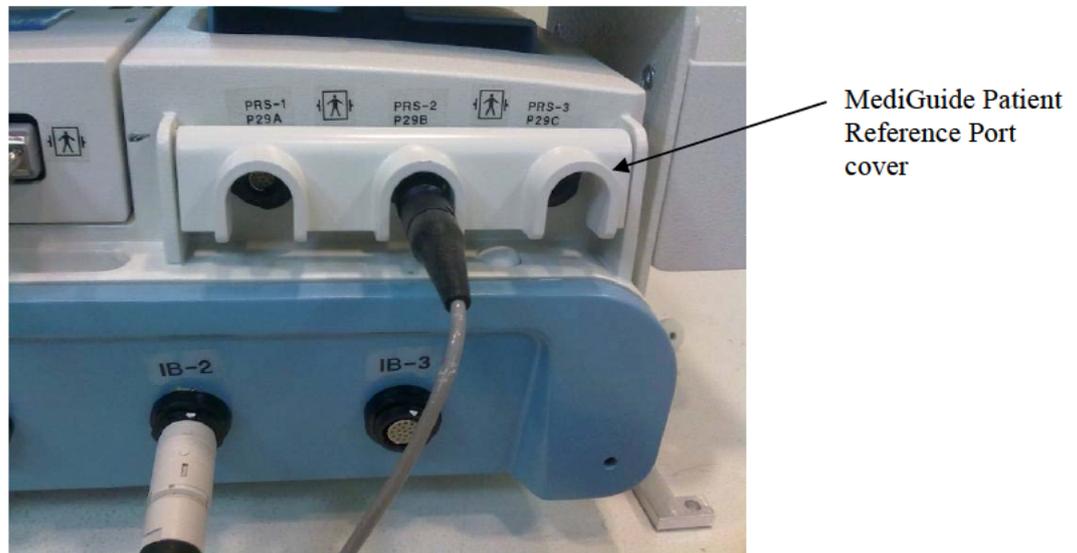


Figure 4-7: MediGuide Patient Reference Connection to MediGuide Connect

Note: MediGuide Patient Reference attachment should only be attached with a MediGuide Patient Reference Patch.

The MediGuide Patient Reference has a jag and the patch has a matching groove to ensure that the MediGuide Patient Reference is inserted at the right angle, as shown in Figure 4-8.

3. Attach the MediGuide Patient Reference patch to the patient’s chest as shown in Figure 3-8. The MediGuide Patient Reference cable should be routed where it does not cause visual interference, and secured with tape. Please refer to instructions in Section 4 below.

WARNING: Do not place the MediGuide Patient Reference Patch on skin with erythema, lesions or injuries.
Do not use the MediGuide Patient Reference on patients with skin



irritation upon direct contact with the MediGuide Patient Reference Patch .

WARNING:



Inspect the MediGuide Connect and its cables before connecting the MediGuide Patient Reference to the MediGuide Connect. If the MediGuide Patient Reference or its cable is damaged, replace with a new MediGuide Patient Reference.

Using a damaged MediGuide Patient Reference may result in an electric shock to the patient.

CAUTION:



Make sure that blankets, sheets, etc. do not touch or cover the MediGuide Patient Reference on the patient's body. Covering or touching the MediGuide Patient Reference may harm accuracy of projection on cine.

Note:

The MediGuide Patient Reference patch has a printed arrow pointing to "HEAD", as shown in Figure 4-8. Affix the patch to the patient's chest with the arrow pointing up

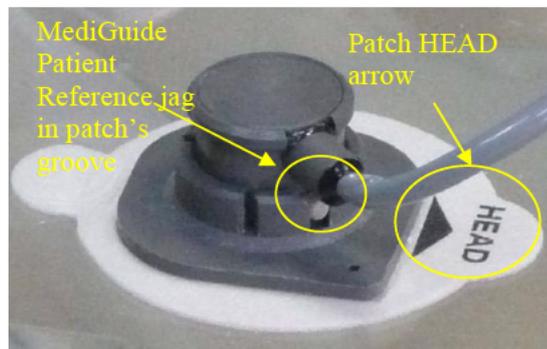


Figure 4-8: Patch with MediGuide Patient Reference attached

CAUTION:



The MediGuide Patient Reference is intended for multiple uses. Therefore, it must be cleaned after each patient as described in MediGuide Patient Reference Maintenance on page 5-1

CAUTION:



In order for the system to operate properly, it is essential that the MediGuide Patient Reference is not moved. If the MediGuide Patient Reference is moved or its patch detached from the patient's body, projection on cines acquired previously will be inaccurate. In such an event, to use cine background, record new cines after the MediGuide Patient Reference has been re-attached and DO NOT use the previously acquired cines.

4. Select the PRS number from the Tools Setup dialog box (see Figure 4-9). The dialog box opens automatically at procedure startup, and can later be opened at any time using the Tools Setup button.

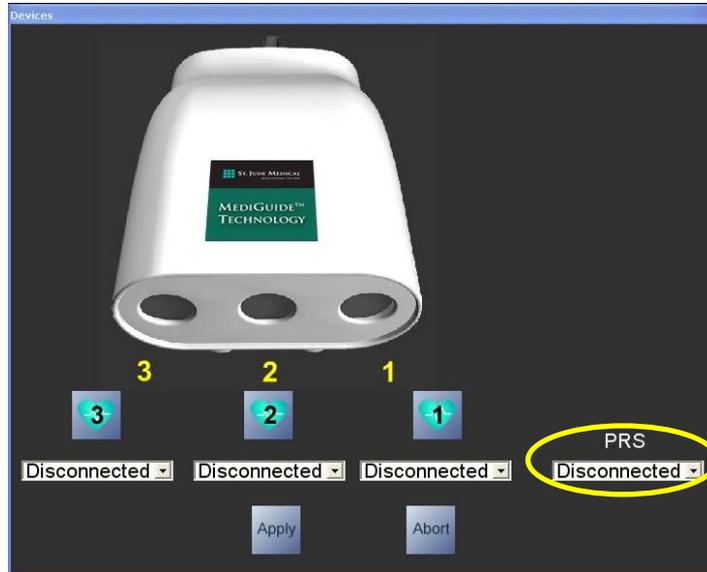


Figure 4-9: PRS Selection

4.3.2 ECG Connection

1. Verify the MediGuide ECG cable is connected to MediGuide ECG in the MediGuide Connect, as shown in Figure 4-10.

CAUTION:



While handling the ECG, ensure that conductive parts of the ECG cable do not contact other conductive parts, including ground, during MediGuide procedure.

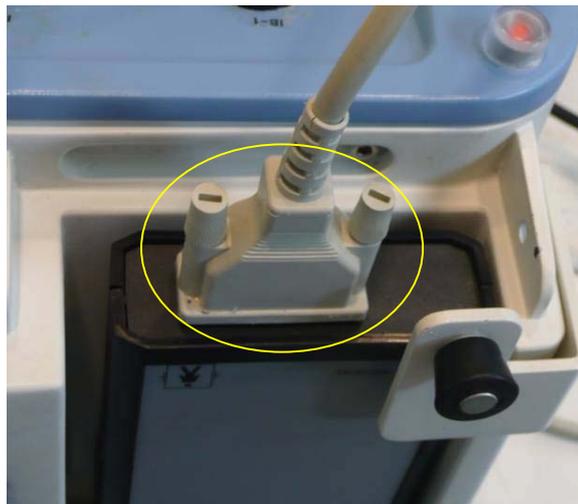


Figure 4-10: MediGuide ECG cable connection

2. Attach the MediGuide ECG electrodes to the patient's chest as shown in Figure 4-11.

Note: MediGuide ECG leads are attached to the patient's body using standard off-the-shelf ECG patches.

3. Attach the 3 MediGuide ECG leads to the electrodes according to their label.

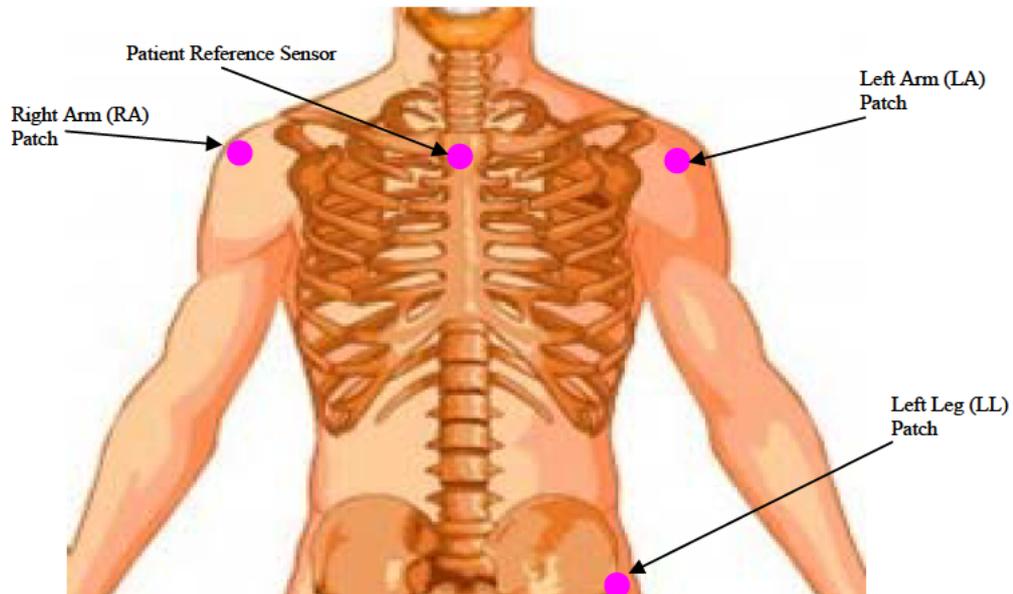


Figure 4-11: MediGuide ECG Leads and MediGuide Patient Reference Locations

4. Verify the ECG has a good signal (see Figure 4-12), clean of noise, and the HR shown by MediGuide ECG matches with the one shown by the Cath Lab's ECG. If not, refer to Section 7.1 for ECG troubleshooting.
5. Verify the MediGuide Patient Reference and MediGuide ECG leads are correctly connected.
6. Secure the wires to the body with tape, approximately 5 cm from the patch. Route the wires away from the MB area (close to the throat and shoulders) in order to assure that no visual interference will be caused by the cables.

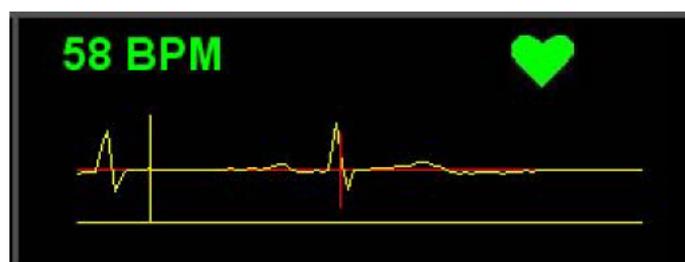


Figure 4-12: A good ECG signal

4.3.3 MediGuide Cath Connect Preparation

1. Verify the MediGuide Cath Connect is properly connected to the Electronics Box (MediGuide Connect) – The MediGuide Cath Connect cable should be inserted to one of the MediGuide Connect connectors with a "MediGuide Cath Connect" label.
2. Place the MediGuide Cath Connect on the end of the Patient Table (near the patient's feet).

CAUTION:



Verify the MediGuide Cath Connect is placed on the table in a stable position, and handle with care to minimize the risk of falling and/or being damaged.

Ensure a minimal distance of 28 inches (70 cm) between the MediGuide Cath Connect and the MTA, when the C-arm is positioned at 45° caudal.

WARNING:



The MediGuide Cath Connect is non-sterile. Care must be taken when disconnecting devices to keep the connector-end of the MediGuide cable outside of the sterile field in order to avoid contamination .

4.3.4 MediGuide Enabled™ Device Connection

1. Connect the MediGuide Enabled™ device to the MediGuide Cath Connect by pushing the connector to its mate in the MediGuide Cath Connect until it locks in. In order to adjust the mating orientation, a gentle rotation of the connector might be needed.

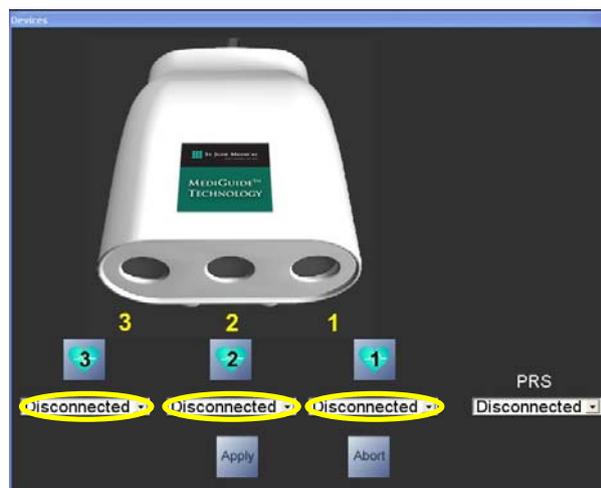


Figure 4-13: Tools Setup

NOTE Consult with the MediGuide Enabled Device's Instructions for Use for specific details regarding its connection

2. Verify the device identification in the **Tools Setup** dialog box (see Figure 4-13 matches the connected device.

NOTE Up to three devices may be connected to the MediGuide Cath Connect simultaneously. Devices may be disconnected and reconnected throughout the procedure.

3. Verify that the system indicates recognition of MediGuide Enabled™ devices by a change in the relevant device field status from Invalid to one of the following statuses, depending on the sensor's position:
 - ◆ Out of MB
 - ◆ MB Margin
 - ◆ Valid



Figure 4-14: MediGuide Cath Connect

4.4 MediGuide Graphic User Interface (GUI)

As indicated in Section 2.4, the System includes two displays, the Primary Display and the Secondary Display.

The controls on the Primary display are organized around the main display screen (see Figure 4-16). The toolbars along the bottom control various operations during

the procedure. On the left, a vertical cine-loop list enables selection of pre-recorded cine loops for playback on both the Primary and Secondary Displays.

The Secondary Display displays a status bar under the main display screen.

Figure 4-16 and Figure 4-17 show an example of a Primary and a Secondary Display layouts, respectively, that feature a typical MediGuide Live Fluoroscopy image and a typical 3D display, respectively.

The System GUI consists of the following sections:

4.4.1 Display Windows

The Display Window is the main part of the viewed area and shows 2D and 3D displays. The display window on the Primary Display displays real-time fluoroscopy and cine-loops. The display window on the Secondary Display displays 3D objects and, when selected, a dual cine display.

Warnings and system messages – displayed as either an interactive pop-up messages or as notifications.

Turn Magnets Off – this control enables immediate shut-off of the MediGuide magnetic field (see Figure 4-4 above). This might be needed when there is a concern of an interference caused by the magnetic field.

Detector Zoom [15FD]; [20FD]; [25FD] – manually synchronize MediGuide zoom to the X-ray detector zoom (see Figure 4-15).



Figure 4-15: Detector Zoom

Note: Detector Zoom buttons are indicative only when working with Siemens Axiom Artis system.

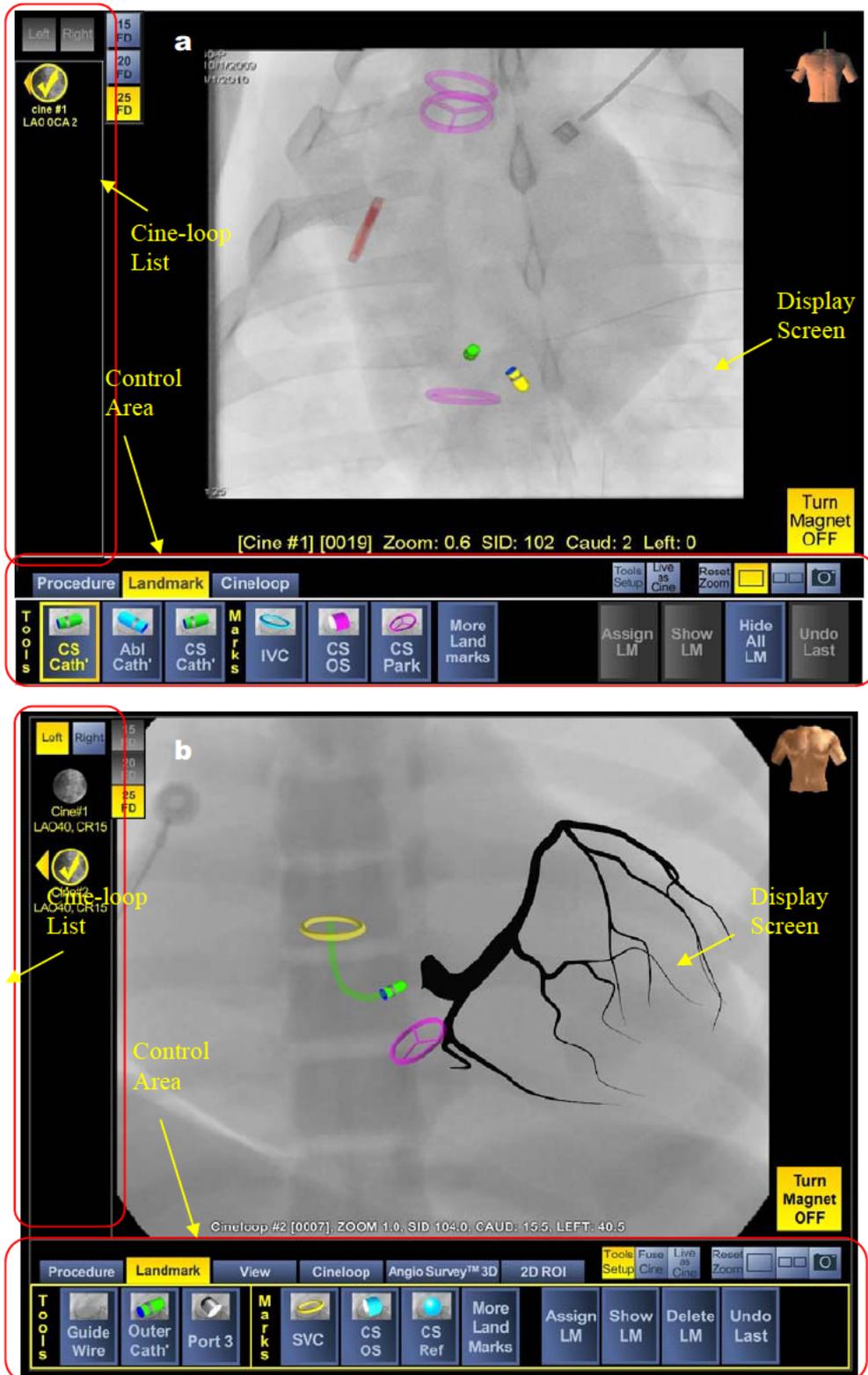


Figure 4-16: MediGuide Primary Display Layout – (a) Cardiac Navigation Application; (b) Cardiac Navigation with Angio Survey™ Application

4.4.2 Cine-loop List

The **Cine-loop List** is a list of cine-loops recorded during the procedure (see Figure 4-16 above, or an enlarged view in Figure 4-18 below). A specific cine-loop can be selected by clicking the corresponding cine-loop icon. When **Dual** cine is selected, the **Cine-loop List** enables selecting a cine separately for the left and right display screens (see Figure 4-18).

4.4.3 3D Model List

The **3D Model** list (see Figure 4-19) is a list of 3D models reconstructed using the application. The user can select a specific model from the 3D model list. The selected model will be displayed on all active display windows.

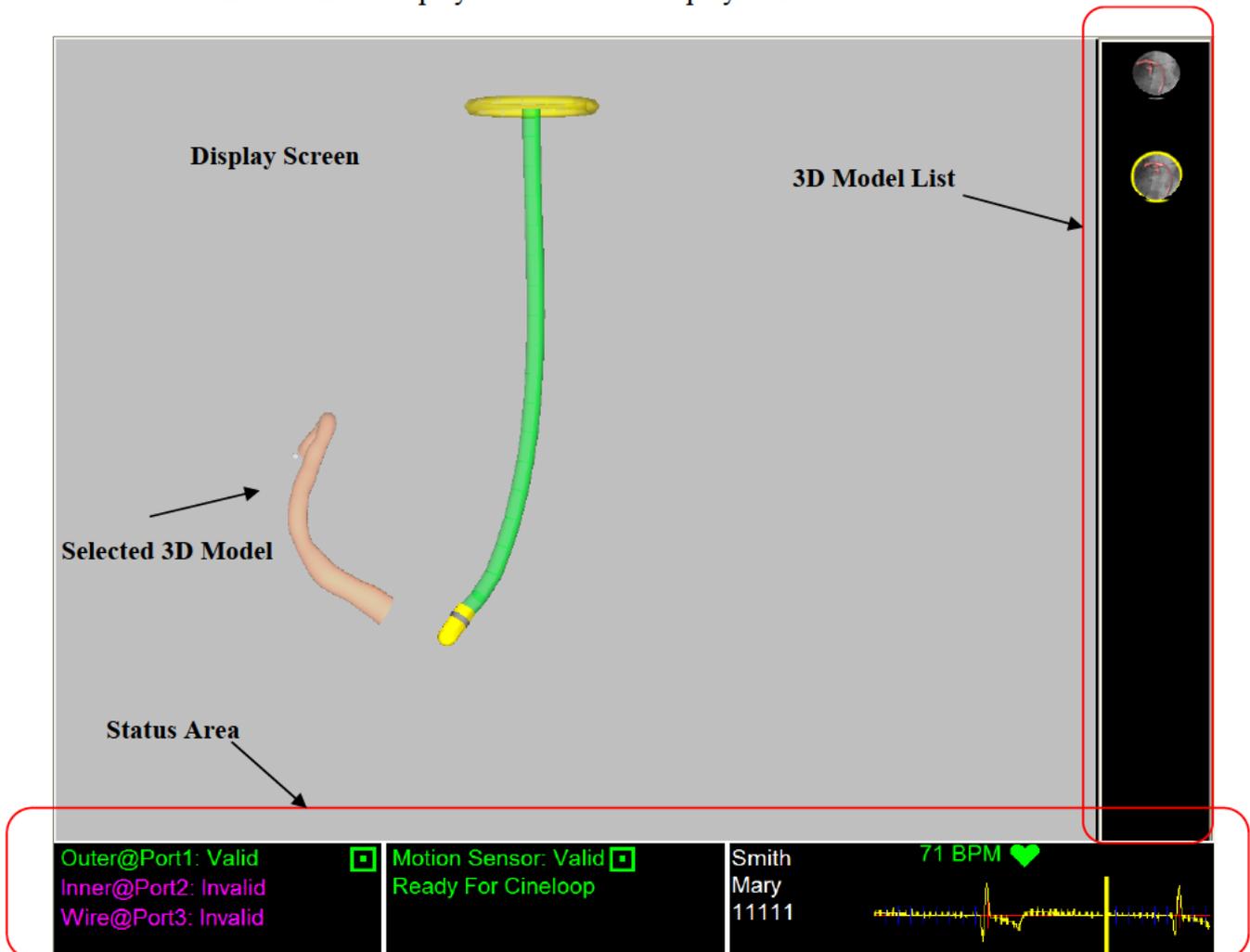


Figure 4-17: Secondary Display Layout

Note: 3D Model List is only available for the Cardiac Navigation with Angio Survey™ Application

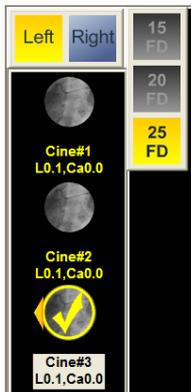


Figure 4-18: Cine-loop List

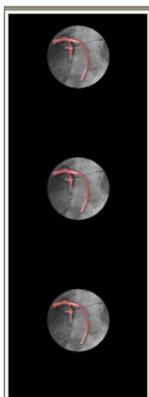


Figure 4-19: 3D Model List

4.4.4 Status Area and Procedure Information

Available on the Secondary Display only, this area provides status and information pertaining to the following system elements: MediGuide enabled device status, Motion Sensor (MediGuide Patient Reference) status, ECG status as well as Heart Rate and the ECG record, readiness for cineloop in terms of respiration correction status, Patient ID, Patient Name, Detector out of range warning in case SID is too high.

4.4.5 Control Area

The Control Area is located on the Primary Display. It is divided into two regions, a top banner providing useful operations available throughout the procedure, and a bottom banner, where the structured functionality tabs and toolbars reside. The controls on the top banner are available during the entire procedure, and include:

- ◆ **Tools setup**  – opens a dialog box where the connections of MediGuide Enabled™ devices to the MediGuide Cath Connect™ ports can be configured.
- ◆ **Screen Capture**  – saves the current screens to an image file.
- ◆ **Live as Cine**  – A toggle button. When selected, any fluoroscopy run will be regarded by the system as a cine. It will be added to the cine list (provided the right conditions), and played back.
- ◆ **Single Cine** , **Dual Cine**  – controls whether a single cine or dual cine is displayed.
- ◆ **Reset Zoom**  – sets the zoom in the Secondary Display screen to match the zoom of the fluoroscopy-based display screen (Primary Display).
- ◆ **2D Fusion**  – activates the Angio Survey™ 2D Fusion feature (only available for the Cardiac Navigation with Angio Survey™ Application – see Section 3.3.9)

The bottom banner includes the main procedure workflow controls, set up as **Tabs** dividing the controls according to their functionalities. Each **Tab** includes a group of **Buttons**, used to activate specific MediGuide operations and settings. Each button is assigned a specific operation, indicated by a label and/or symbol. The status of the buttons visually indicates as follows (see Figure 4-20):

- ◆ Enabled buttons are indicated by white faced characters and symbols on a blue background
- ◆ Currently selected (active) buttons are indicated by yellow faced characters and symbols and a circumscribing yellow frame on a blue background

- ◆ Disabled buttons are grayed out
- ◆ Selecting an enabled button activates its stated operation, or displays a pop-up dialog, which requires additional user interaction.



Figure 4-20: Button Different Status

In addition to **Buttons**, **Sliders** are controls specifically designed to be used in selection of a specific frame from a cine-loop.

The **Tabs** are used to arrange the control into functionality groups:

NOTE The specific available controls may vary according to the application. The following figures serve for visualization only.



Figure 4-21: Procedure Tab

- ◆ **Procedure** Tab (see **Figure 4-21**) controls the entire procedure, such as starting and ending a procedure, backing up and restoring. It includes the following operations:
 - a) **New** – start a new procedure
 - b) **Open** – open a previous procedure for viewing
 - c) **Close** – close a current procedure
 - d) **Archv** – archiving a procedure on removable media, or reading an archived procedure from removable media
 - e) **Tools** - open a utility dialog box
 - f) **About** – provide information regarding the software version
 - g) **Exit** – Exit application and return to MediGuide Technology screen
- ◆ **Landmark** Tab (see **Figure 4-22**) includes buttons for assignment, deletion, showing and hiding landmarks, in addition to frequently used landmarks, and a

More Landmarks button for selecting less frequently used landmarks (see Figure 4-23).



Figure 4-22: Landmarks Tab

- ◆ **View** Tab (see Figure 4-24) controls whether graphic objects generated during the procedure are visible or not. Each graphic object may be turned on or off using the buttons on this tab.
- ◆ **Cineloop** Tab enables the selection of a specific frame and stopping a cine playback. It has separate controls for the primary and secondary (if active) cine displays. When the **Road Map**  button is selected, the cine playback is stopped and a certain frame can be selected using the slider or the frame up/down buttons. All P&Os of MediGuide Enabled™ devices and landmarks are projected on the selected still frame. Figure 4-25 shows the **Cineloop** tab when a single cine view is selected, and Figure 4-26 shows it when dual cine view is selected.
- ◆ **AngioSurvey™ 3D** Tab provides access to all the buttons controlling the flow of 3D model reconstruction, and displays relevant text messages. Figure 4-27 shows an example of one of the steps of the process.



Figure 4-23: More Landmarks Dialog Box

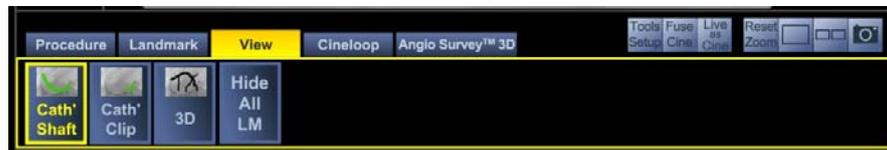


Figure 4-24: View Tab¹



Figure 4-25: Cineloop Tab (single cine)



Figure 4-26: Cineloop Tab (dual cine)

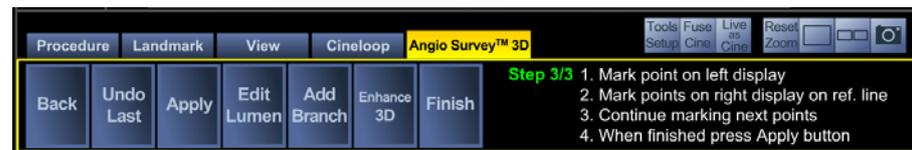


Figure 4-27: Angio Survey™ 3D Tab¹

4.5 Key Features Available During the Procedure

After the preparation steps are performed and at least one MediGuide Enabled™ device is connected to the system and inserted into the patient, the following features are available:

4.5.1 Fluoroscopy

The user may take, at any time during a MediGuide procedure, a fluoroscopic view of the anatomy using the standard C-arm fluoroscopy pedal. The fluoroscopy images will be displayed on the Display Screen of the Primary Display.

¹ This feature is only available for the Extended Cardiac Application

During fluoroscopy, any MediGuide Enabled™ device present in the imaged anatomy will be tracked on the fluoroscopy images. Whenever Shaft Rendering is applicable (depending on the application in use, the MediGuide Enabled device and the flow), the shaft of the device will be rendered as well. To hide the rendered shaft, select the **Cath' Shaft** button on the **View** tab.

4.5.2 Cine Recording and Playback

The user may record, at any time during a MediGuide procedure, a fluoroscopic cine of the anatomy using the standard C-arm cine recording pedal. During recording, the cine will be displayed on the Display Screen of the Primary Display like fluoroscopy. Recording status messages are displayed on the top right corner of the display screen.

After the recording is complete, the cine is added to the cine-loop list (see Figure 4-18). The cine is played back in a loop in synchronization with its real-time ECG.

Any cine-loop may be selected from the cine-loop list at any time. The most recently selected cine will be played back in a loop. When **Dual Cine** is selected (see Section 4.4.2), a cine-loop may be selected for playback in each Display Screen separately. To select a cine for a certain Display Screen, use the **Left/Right** button at the top of the **Cine-loop List** (see Figure 4-18).

The user may select a roadmap image from the selected cine, to be displayed as a still image.

When a cine-loop is played back, any MediGuide Enabled™ device present at the imaged anatomy will be tracked on the cine-loop. If a roadmap image was selected, MediGuide Enabled™ devices will be tracked on the roadmap image. In addition to MediGuide enabled devices, other 3D objects such as **landmarks** (see Section 4.5.3) will be also displayed on the underlying selected images.

4.5.3 Landmark Placement

The user may place landmarks of any anatomical features. Landmarks may be placed using MediGuide sensor P&Os. To place a landmark, locate the tip of the MediGuide Enabled™ device at the anatomical location where the landmark needs to be placed,

select the MediGuide Enabled™ device under the Landmark tab, then press the appropriate landmark button followed by the assign button.

Once a landmark is assigned, it may be displayed on both 2D and 3D display windows. Figure 4-28 shows an example of Landmarks projected on cine. Figure 4-29 shows the same Landmarks in 3D.

An assigned landmark can be deleted by selecting the landmark button and then selecting the **Delete LM** button.

To hide a landmark, select the **Hide LM** button.

To show a hidden landmark, select the **Show LM** button.

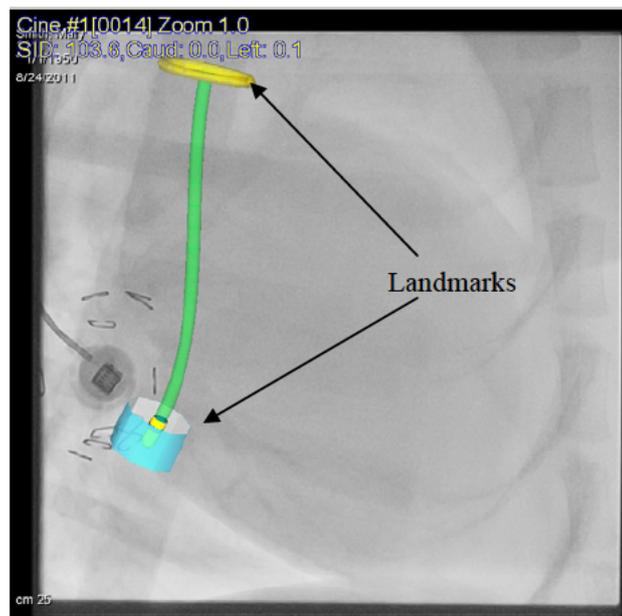


Figure 4-28: 2D Display including landmarks

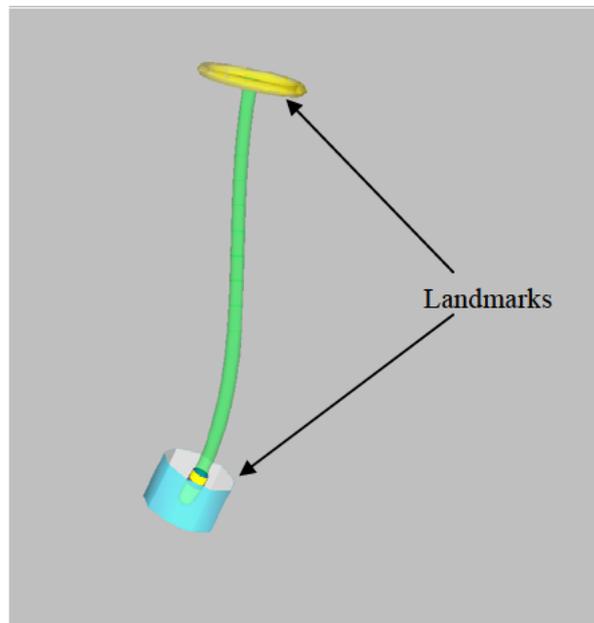


Figure 4-29: 3D display including landmarks

4.5.4 Angio Survey™ 2D Fusion

Note: This feature is only available for the Cardiac Navigation with Angio Survey™ Application

Angio Survey™ 2D Fusion enables the user to view live fluoroscopy with an overlay of matched pre-recorded fluoroscopy. This feature can be used to fluoroscopically view the tools used in the procedure with an overlay showing an angiogram or venogram of a relevant vascular anatomical structure, e.g., the coronary sinus (CS). This enables the user to locate the tools with respect to the anatomy. To use the Angio Survey™ 2D Fusion, the following steps need to be performed:

1. Record a cine-loop imaging a desired anatomy (for example, a venogram of the CS) from your preferred projection.
2. Without moving the C-arm or the patient, select the **Fuse Cine** control as seen in Figure 4-30.



Figure 4-30: Fuse Cine Control

3. When live fluoroscopy is used, the recorded cine-loop will be overlaid on the live images. The overlay will be displayed in shades of green. Manipulate the tools as needed using the anatomical information projected by the fused cine.

Note: Moving the C-arm, the patient or the table will disable the operation of the Angio Survey™ 2D Fusion.

4. To control the opacity of the overlay, use the arrow controls at the left of the display (see Figure 4-31).

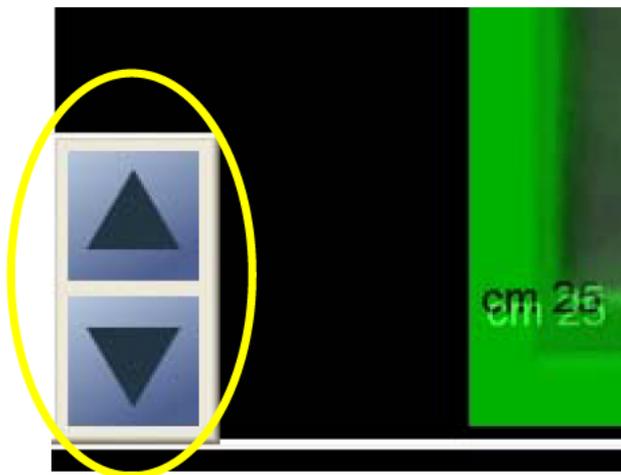


Figure 4-31: Angio Survey™ 2D Fusion Opacity Control

5. To deactivate the Angio Survey™ 2D Fusion, select the **Fuse Cine** control again.

4.5.5 Angio Survey™ 3D

Note: This feature is only available for the Cardiac Navigation with Angio Survey™ Application

With Angio Survey™ 3D, it is possible to reconstruct a 3D model of a vascular anatomy using two cine-loops taken from different projections. The reconstructed model can then be displayed in 3D or be projected on fluoroscopy, live or pre-recorded.

To reconstruct an Angio Survey™ 3D model, the following steps need to be performed:

1. Record two cine-loops displaying the desired anatomy, keeping in mind the following:
 - a. The cine-loops have to be taken at least 40° apart.
 - b. Each cine-loop has to highlight all parts of the anatomy of interest.
 - c. It is recommended to select projections where the region of interest in the anatomy has the overall minimum foreshortening.
2. Select the Angio Survey™ 3D tab (see Figure 4-32).
3. Select the **Create Model** button.
4. Select the cine-loop with the least foreshortening of the two to be displayed on the left display, and the other on the right display. If the cine-loops are less than 40° apart, a message will indicate that reconstruction cannot be performed. Otherwise, the **Next** button will be enabled.
5. Select **Next**
6. Using the frame controls, select a frame on the left cine-loop. Once selected, only frames matching the cardiac phase of the selected frame will be available on the right cine-loop.
7. Select a frame on the right cine-loop.



Figure 4-32: Angio Survey™ 3D

8. Mark the region of interest (ROI) (see Figure 4-33):
 - a. Starting from the proximal part of the anatomy, mark a point on the left cine-loop by clicking the left mouse button.
 - b. A line crossing the anatomy (epi-polar line, the projection of the point selected on the left cine-loop) will appear on the right cine-loop image. Its crossing point with the vessel serves as a hint to where the

corresponding point should be marked. Mark the point on the right cine-loop.

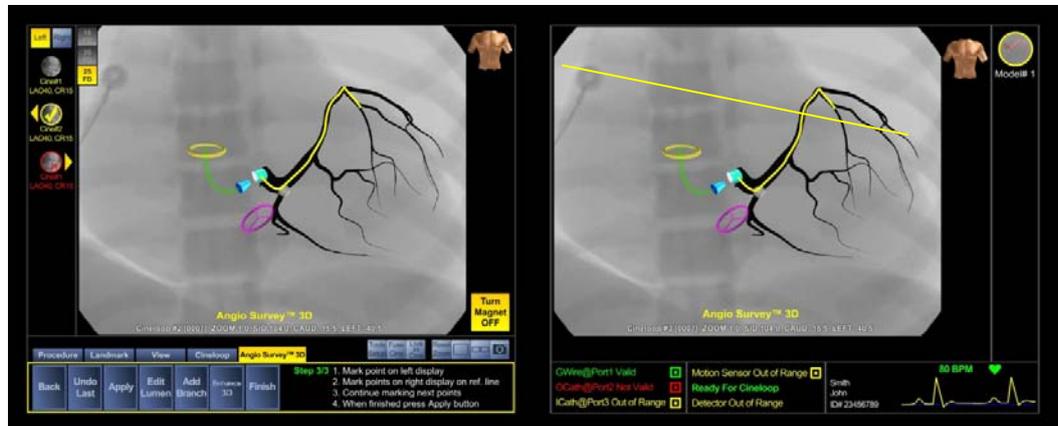


Figure 4-33: Angio Survey™ 3D – Marking ROI

Note: The epipolar line is an approximation of the plane on which the corresponding point may be located. Use it only as a hint and mark the exact corresponding point based on his or her judgment.

c. Repeat steps a and b until the ROI meets your needs.

Note: If a point was entered incorrectly, select the **Undo Last** button .

d. Select the **Apply** button to reconstruct the model. The projection of the reconstructed model will show on both cine-loops (see Figure 4-34).

Note: If the lumen boundaries of the model deviate from the actual vessel boundaries, use the **Edit Lumen** button to correct them on the primary display. Lumen is edited by dragging the mouse with the left button pressed over the correct path of the wall.

1. To add a branch to the reconstructed model (see Figure 4-35):
 - a. Select the **Add Branch** button.
 - b. Mark points along the desired branch using the mouse on the left cine-loop.
 - c. Mark the corresponding points on the right cine-loop, with the help of the epi-polar lines that will display.
 - d. Select the **Apply** button to create the branch.
 - e. If needed, adjust the branch's boundaries by dragging them using the mouse.

- f. Select the **Apply** button.
- g. To add multiple branches, repeat steps a through f.

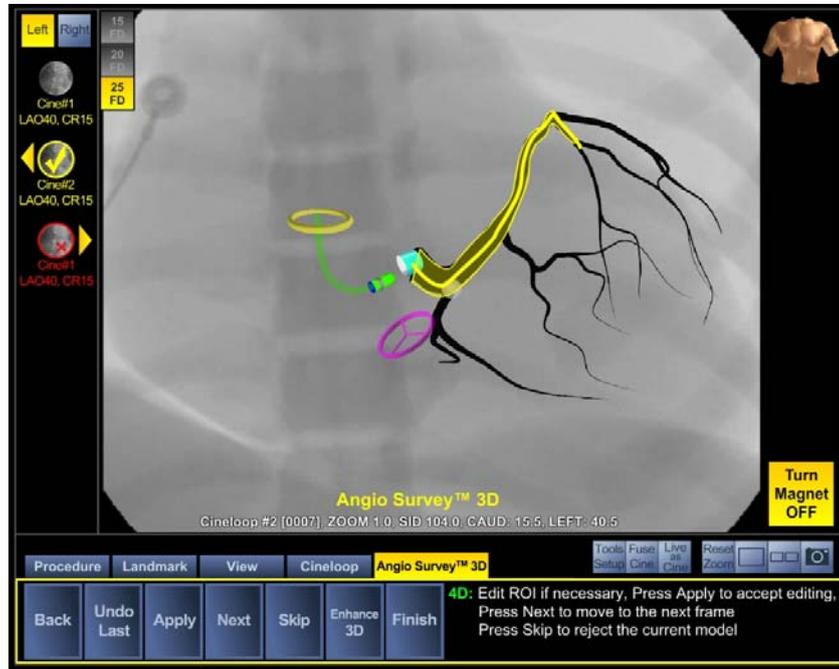


Figure 4-34: Angio Survey™ 3D model projection on cine-loop

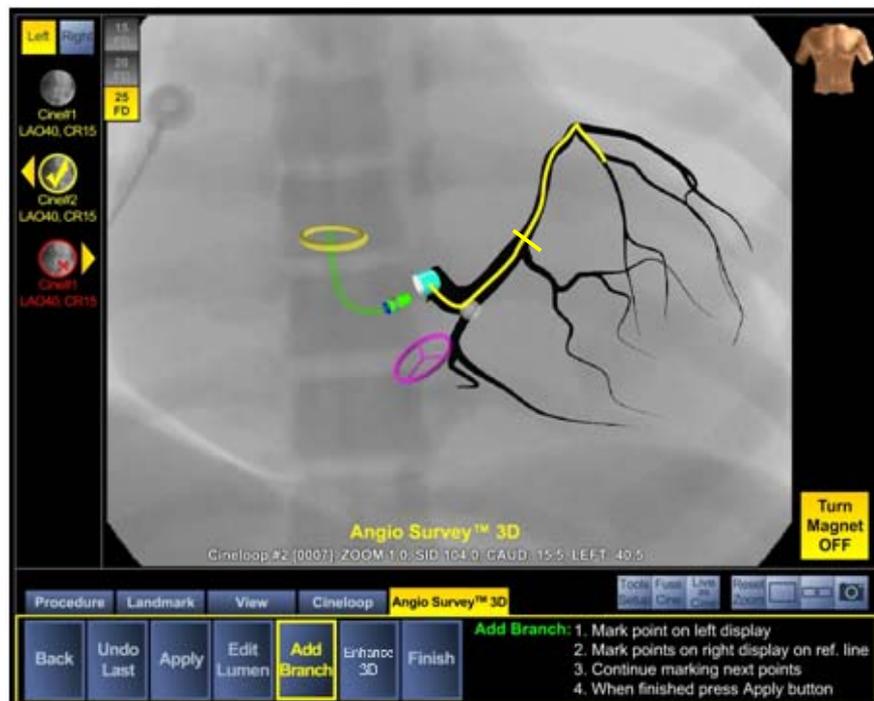


Figure 4-35: Angio Survey™ 3D Add Branch

2. To create an enhanced 3D model that will pulsate according to the cardiac cycle, select the **Enhance 3D** button and perform the following steps:

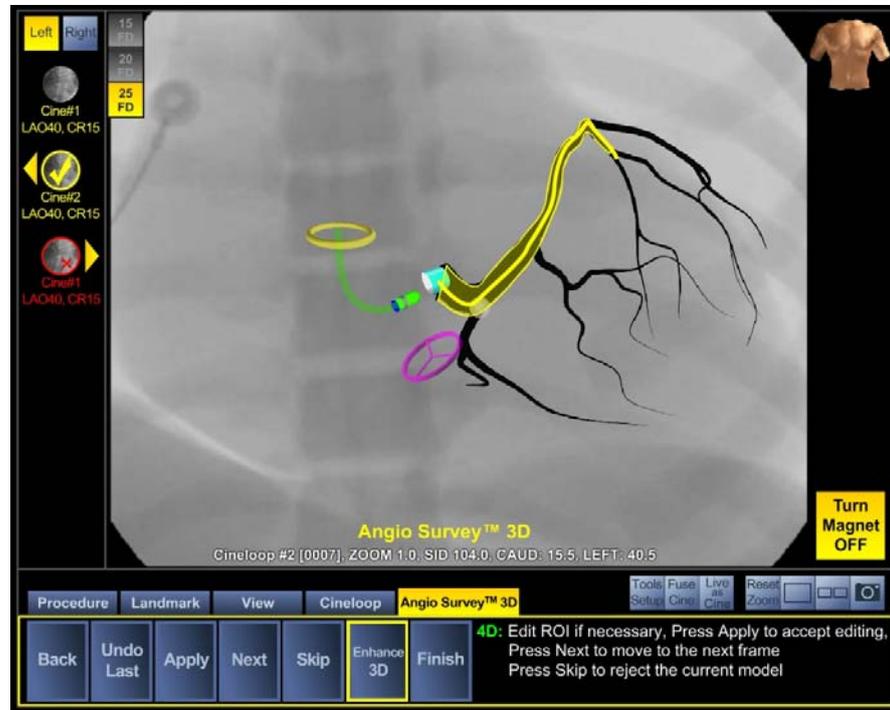


Figure 4-36: Angio Survey™ Enhance 3D model

- a. A computed ROI will display on a pair of images that follows the pair on which the ROI was first marked. If the ROI is correct, select **Next**, otherwise edit the ROI similarly to the initial ROI marking.
- b. Repeat step a until the message *Enhance 3D complete on one ECG cycle* appears on the banner at the top of the left display window.
- c. select **Finish**

4.6 MediGuide Procedure Guidelines

4.6.1 Setup

1. Follow the System startup and patient preparation steps as described in Section 4.3.
2. Start a new MediGuide procedure by selecting the **New** button.
3. Fill in procedure data in the appropriate fields in the dialog box (see Figure 4-37).

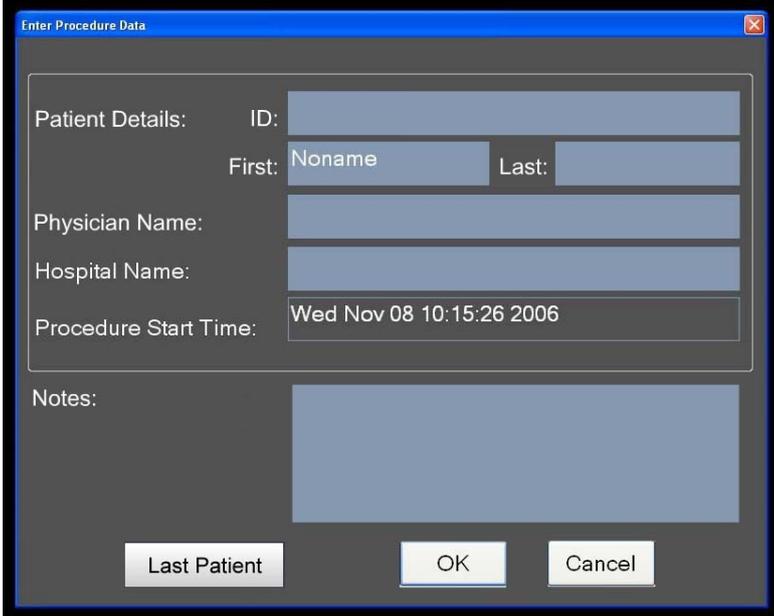


Figure 4-37: New Dialog Box

4.6.2 MediGuide Enabled™ Device Connection and Use

1. Connect, reconnect or disconnect a MediGuide Enabled™ device whenever appropriate during the procedure.

Note: Before using a device invasively, it is recommended to test its functionality after it is connected to the MediGuide Cath Connect, by placing it under the imaging system's detector and verifying that the status has changed from INVALID.

2. Configure the device type (select the relevant type of device from the list that opens below each MediGuide Cath Connect port) and connection port using the **Tools Setup** dialog box (see Figure 4-9).

Note: The available MediGuide Enabled™ devices for selection will be configured by a technician, according to device availability and procedure type.

3. Use the MediGuide Enabled™ devices according to the device's user manual, and observe their tracking on the relevant System displays. Once a MediGuide Enabled™ device is connected and placed in the Motion Box, it will be tracked by the system and displayed in all active display screens, either in 3D or superimposed on fluoroscopy.

Note: Like any other invasive device, MediGuide Enabled™ devices may be tracked on the imaging system’s displays using standard fluoroscopy.

4.6.3 Fluoroscopy Recording and Viewing

- ◆ During the procedure, fluoroscopy may be used . To take advantage of the System’s capability of displaying device and landmark tracking on previously acquired fluoroscopy, record one or more cine loops from any selected C-arm angulation within the range specified in **Section 3.5**. The most recently recorded cine will be played back on the Primary Display . A different cine may be displayed by selecting it from the cine-loop list. Whenever live fluoroscopy is taken, whether using the fluoro pedal or the cine pedal, it will be displayed instead of the cine on the Primary Display, with the MediGuide Enabled™ devices and landmarks superimposed.
- ◆ To record a cine:
 - a) Position the C-arm at the desired angulation.
 - b) Wait 30 seconds for the indicator on the status area to read “Ready for Cineloop” in green (see Figure 4-38).



Figure 4-38: “Ready For Cineloop” indicator

- c) Press the cine pedal and hold until the “Recording Cine” banner turns green. The cine will be added to the **Cine-loop List** and will be played back on the primary display.
- d) If the cine is too short, it will not be added to the cine list and an error message will be displayed.
- e) If during the cine recording an abrupt change of the patient’s ECG, respiration or position has occurred, the “Recording Cine” banner will turn cyan and read “Cine will not be validated”. The cine will be added to the **Cine-loop List** with a red “X”. It will not be automatically played back. To select this cine, select the icon on the cine list.

NOTE: It is possible to record a cine using the regular fluoroscopy pedal. To do that, press the **Live as Cine**  button in the control area, as explained in Section 4.4.5. As long as this button is selected, any fluoroscopy will be recorded as a cine, added to the cine-list and be used as background for projection.

CAUTION: Using a cine with a red “X” might result in deteriorated projection accuracy .



- ◆ As long as Dual cine view is not selected, a 3D display of the MediGuide Enabled™ devices and landmarks will show on the display screen of the Secondary Display.
- ◆ To select a Dual cine view, use the **Dual**  button in the top banner of the Control Area. A cine can be selected for display on the Secondary Display from the cine-loop list, using the **Right** button at the top of the cine-loop list (see Figure 4-18). Whenever two cine loops are selected, they will both be played back with MediGuide Enabled™ devices and landmarks superimposed.
- ◆ If **Dual** cine view is selected, whenever live fluoroscopy is taken, it will show on the Primary Display, while the cine selected for the Secondary Display will continue playing.
- ◆ To use a still image instead of a cine playback for projection background, use the **Road Map** button on the **Cine** slider in the **Cineloop** Tab. See Figure 4-25 and Figure 4-26 for cine control in single and dual view modes.

4.6.4 Landmark Assignment

Landmarks may be assigned at any anatomical point. To assign a landmark:

- a) Select an available MediGuide Enabled™ device from the **Landmarks** Tab. In the example shown in Figure 4-39, there is one available outer catheter device, connected to MediGuide Cath Connect port #2, and one available Guidewire device, connected to MediGuide Cath Connect port #1.



Figure 4-39: MediGuide-Enabled Device for Landmark Assignment

- b) When the device tip is positioned at the target anatomy, select the appropriate landmark button available in the **Landmarks** Tab (e.g., CS OS – refer to Section 0 for the complete list of available landmarks), and select the Assign LM button.
- c) From this point on, the landmark will be displayed on all active System displays.
- d) To disable viewing the landmark, unselect it using the Show/Hide button.
- e) To delete the landmark select the Delete button.

To cancel the last operation, select Undo Last.

4.6.5 Closing the Procedure

After the clinical procedure is done, the procedure can be closed using the **Close** button on the **Procedure** Tab (see Figure 4-21 above). Alternatively, the application may be terminated using the **Exit** button. A closed procedure will be saved on the system's hard drive for future viewing or archive operations. To view a closed procedure, select the **Open** button on the **Procedure** Tab and select the procedure from the list in the dialog box.

4.6.6 Post-Procedure Operations

After a procedure has been closed, it may be backed up on removable media using the **Archv** button. The **Archive** dialog box that opens (see Figure 4-40) enables MediGuide **Database** Operations which include the following:

- ◆ **Export** – stores a selected procedure on removable media
- ◆ **Import** – restores a selected procedure from removable media
- ◆ **Delete** – deletes a procedure from the system's hard drive. This operation is password-protected
- ◆ **Change Password** – changes the administrator password for Delete operations

See Section 5.2 for more details about database operations.



Figure 4-40: Database Operations

5 User-Level Maintenance

Note: Maintaining the system on a periodic basis, both by the user and by MediGuide Ltd., is crucial for keeping full system performance. It is advised to follow MediGuide's instructions for periodic maintenance, in order to avoid low system performance, and in order to verify high system reliability over time.

It is the responsibility of the user to perform the following maintenance operations:

- ◆ MediGuide Patient Reference Maintenance on page 5-1
- ◆ Data Management on page 5-2

All other maintenance operations should be performed by a qualified technician only.

CAUTION: Do not perform any kind of maintenance to the system in the presence of explosive materials.



5.1 MediGuide Patient Reference Maintenance

The MediGuide Patient Reference is intended for multiple use. Therefore, it must be cleaned and maintained as follows:

- ◆ Clean the MediGuide Patient Reference by wiping it, except its connector, with a cloth saturated with 70% alcohol solution, **at the end of each use**. Inspect the MediGuide Patient Reference and its cable to verify that it is mechanically intact. Store in the pouch, while still connected to the MediGuide Connect, on the Table Rail. If the MediGuide Patient Reference or its cable is damaged, replace the MediGuide Patient Reference.
- ◆ Disconnect the MediGuide Patient Reference from the MediGuide Connect and store it in its package **at the end of the day** after cleaning it.
- ◆ It is recommended to clean the MediGuide Patient Reference with a cloth saturated with **2% glutaraldehyde** solution (such as Cidex) **once a month**.

5.2 Data Management

Deleting MediGuide procedures from the hard disk should be performed on a periodical basis, according to hospital policy, considering disk size and disk space utilization. If a “Free disk space” warning appears, the application will not allow the user to open a new procedure until enough disk space is available.

For usage convenience, the recommended policy is:

- ◆ Each procedure may be backed up on a removable media, as specified in Export a MediGuide Procedure to Removable Media on page 5-2
- ◆ When a procedure had been backed up successfully, it should be removed from the hard disk, as a delete operation is automatically asserted by MediGuide application. For detailed instructions, refer to Delete MediGuide Procedures from the Hard Disk on page 5-4.

5.2.1 Export a MediGuide Procedure to Removable Media

The **Export** entry in the **Database Operations** dialog is used to back up MediGuide procedures saved on the hard disk to a removable media.

Note: It is recommended to perform database operations from the Technician Interface Station, since the keyboard and the mouse enable selection of multiple procedures (useful for Delete operations).

1. Select System menu and click the [**Archv**] button.

The Database Operations opens:

2. Select the [**Export**] option from the Database Operations dialog (see Figure 4-40 above) to open the **Export** dialog box as shown in Figure 5-1 below.

The list of all the procedures saved on the hard disk is displayed.



Patient	ID	Date	Physician	Notes
1		24, 11, 2011, 12:03		
1		24, 11, 2011, 11:06		
1		24, 11, 2011, 10:46		
1		24, 11, 2011, 10:38		
1		24, 11, 2011, 10:27		
1		24, 11, 2011, 10:09		
1 d		23, 11, 2011, 22:40	phyua	
1		23, 11, 2011, 21:37		
1		23, 11, 2011, 21:33		
1		23, 11, 2011, 21:09		
1		23, 11, 2011, 20:55		
1		23, 11, 2011, 19:31		
1		23, 11, 2011, 18:45		
1		23, 11, 2011, 18:40		
1		23, 11, 2011, 18:38		
1		23, 11, 2011, 18:21		

Figure 5-1: Export Dialog Box

3. Select the procedure to be saved, and select **[OK]**. The window “Select Destination Folder” opens.
4. Select the destination folder and **[Copy]**.
5. Once export is done, select the **[Back]** button if needed.
6. When backup has been completed, a Delete operation is asserted by MediGuide application. The user can choose to delete the backed up procedure or to leave it on the disk for further analysis.

5.2.2 Import MediGuide Procedures from Removable Media

The **Import** entry in the **Database Operations** dialog is used to retrieve MediGuide procedures from a removable media to the hard disk. For exporting procedures to removable media, see Paragraph 5.2.1.

1. Connect the removable media containing the procedure to the system.
2. Select the **[Import]** option in the Database Operations dialog. The Import dialog box opens (See Figure 5-2).
3. Select the procedure to be imported, and select **[OK]**.

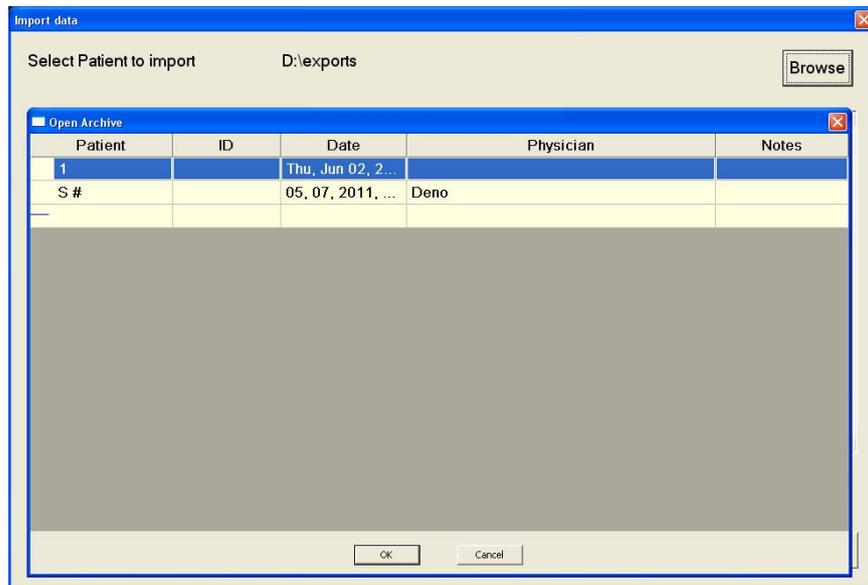


Figure 5-2: Import Dialog Box

5.2.3 Delete MediGuide Procedures from the Hard Disk

The **Delete** entry in the **Database Operations** dialog is used to delete MediGuide procedures from the hard disk, in order to free disk space.



CAUTION: Before deleting any procedure make sure that it had been backed up. A procedure that has not been backed up will be unrecoverable after deletion.

To delete MediGuide procedures from the hard disk:

1. Select the **Procedure** tab on the Primary Display, then select the [**Archv**] button.
The Database Operations dialog opens.
2. Select [**Delete**].
The list of all the procedures currently saved on the hard disk is displayed.
3. While holding down the <Shift> key, select the procedures to be deleted, and select [**Delete**].
A password requesting dialog opens.
4. Enter the appropriate password (assigned by MediGuide Ltd. technician), and select [**OK**].
The selected procedures will be deleted from the hard disk.
5. Select [**Exit**].



6 Feedback

MediGuide is trying to improve its products constantly, in order to maximize user satisfaction.

If you have any comments or suggestions, regarding system usability, reliability, maintainability, or user-interface, please contact MediGuide

In addition, in some cases, MediGuide may use on-site satisfaction forms. Please help us by completing the form with all relevant details.

7 Troubleshooting

Table 7.1 lists the errors that may occur during system operation, their descriptions and the corrective actions to take.

The corrective actions given in the table are listed in a specific order, to be performed one at a time. Starting with the first corrective action, if a certain action does not solve the problem, the user is advised to proceed to the following one.

7.1 MediGuide Troubleshooting

Item #	Error	Description	Corrective action
1.	MediGuide Enabled Device status changes to "Invalid/Out of M.B"	The MediGuide Enabled Device positioning is not displayed on the System Display Screens	Restore the MediGuide Enabled device position into the Motion Box and check the status (verify that the X-ray detector height is less than 15 cm (5.9 inches) above patient's anatomical structure, the inspected organ is in the imaging field of view and the MediGuide Enabled device is in the relevant region). Verify that the MediGuide Enabled device is connected to the MediGuide Cath Connect.
2.	MediGuide Enabled Device projection suddenly disappears	The MediGuide Enabled Device positioning is not displayed on the System Display	Verify that the MediGuide Enabled device is in the MB. If the MediGuide Enabled device status is "Invalid/Out of M.B", refer to item #1 in this table.



Item #	Error	Description	Corrective action
		Screens	<p>Verify that the MediGuide Enabled device is connected to the MediGuide Cath Connect.</p> <p>If the MediGuide Patient Reference status is "Invalid/Out of MB", restore the MediGuide Patient Reference position into the Motion Box. (Verify that the X-ray detector height is less than 15 cm (5.9 inches) above patient's anatomical structure and the inspected organ is in the imaging field of view).</p> <p>Verify that the MediGuide Patient Reference is properly connected to the MediGuide Connect and the patient.</p> <p>Verify the MediGuide ECG signal is valid. If not, verify that ECG leads and electrodes are properly connected to the MediGuide Connect and the patient.</p>
3.	MediGuide Patient Reference status changed to "Invalid/Out of	The MediGuide-Enabled Device positioning is not displayed on the System Display	<p>Restore the MediGuide Patient Reference position into the Motion Box, or as in item #1 of this table.</p> <p>Verify that the X-ray detector is at</p>

Item #	Error	Description	Corrective action
	M.B"	Screens	<p>less than 15 cm (5.9 inches) from patient's anatomical structure.</p> <p>Verify MediGuide Patient Reference is firmly connected to the patient.</p> <p>Verify that the inspected organ is visible on the screen by pressing Live fluoroscopy pedal</p>
4.	"Metal field distortion" message	Message appears on the Secondary Display and MediGuide-Enabled Device positioning performance is poor	Check if metal objects are found in the vicinity of the patient's treated area. If so, remove them, to keep a distance of at least 70 cm (32 inches) between the metallic object and the MTA.
5.	"SID out of limits" message	Message, detailing the valid operational range, appears on the Secondary Display and MediGuide-Enabled Device positioning performance is poor	Adapt the detector position to a valid operational range as indicated by the message.
6.	ECG does not respond after software reset	Message appears on the Secondary Display	<p>Verify the MediGuide ECG recorder power switch is <ON>.</p> <p>Verify the ECG cable is securely</p>



Item #	Error	Description	Corrective action
			connected to the MediGuide Connect.
7.	The HR displayed by MediGuide ECG is too low/high/unstable	Message appears on the Secondary Display.	<p>Compare the MediGuide ECG signal with the ECG signal of the Cath Lab. If the Cath Lab ECG is similar to MediGuide ECG, continue the MediGuide procedure. If the MediGuide ECG is unstable then do the following:</p> <ol style="list-style-type: none"> 1. Verify that all 3 leads of MediGuide ECG are connected to the electrodes and the electrodes are securely attached to the patient's body. 2. Verify t the ECG cable is firmly connected to the MediGuide Connect. 3. Replace right arm with left arm leads or abdomen lead with right/left arm lead 4. Verify whether the patient is arrhythmic
8.	X-ray image is corrupted	The X-ray screen (of the Cath Lab)	<p>Shutdown the System.</p> <p>If the problem persists, verify that</p>

Item #	Error	Description	Corrective action
		presents only white horizontal stripes instead of usual image	the XIU cable is securely connected to the Console. If the problem persists, call a MediGuide authorized technician.
9.	X-ray image on Technician Interface Station of the Imaging System is blank	The technician X-ray screen is blank, although a fluoroscopy is operated	Verify the video cables and splitters (if exist) are connected properly and powered ON. Verify that the Lab doors are closed.
10.	"HW Error" message	Message appears on the Secondary Display	Shutdown the system. Wait for 20 minutes If the problem persists, call a MediGuide's authorized technician.
11.	TSU mouse does not respond to user's selection	The user cannot select MediGuide commands	Verify that the mouse cable is connected to TSU cable. Verify that the Technician Interface Station's mouse is active. If the problem persists, call a MediGuide's authorized technician.
12.	The system does not boot	The user cannot turn ON the system	Verify the mains cable is connected to the Console lower rear input socket.



Item #	Error	Description	Corrective action
			If the problem persists, call a MediGuide authorized technician.
13.	"Insufficient Disk space" message	The user cannot continue normal operation	Close the procedure. Go to Archive, back up procedures to removable media and delete the backed up procedures. If the problem persists, call a MediGuide authorized technician
14.	No communication between MPSC and other Hardware components	The user cannot perform an operation	A detailed message appears on the screen, indicating which device has lost communication with the MPSC. Wait for 30 seconds. If problem is not automatically fixed, turn the system off and wait for 20 seconds, and then restart . If the problem persists, call a MediGuide authorized technician
15.	"Communication error" message	One of the devices has lost communication with the MPSC	Check all cables: MediGuide Connect – around the floor cables area, and under the table. Verify that 4 cables are connected to the bottom of the MediGuide Connect, according to

Item #	Error	Description	Corrective action
			<p>their labels (Ethernet, Sync, TSU, and Power). Verify that all connectors are securely connected. Disconnect and reconnect the cables.</p> <p>MediGuide Cath Connect – by the rail, and around the MediGuide Connect. Verify that the cable is securely connected to the MediGuide Connect front panel (labels MediGuide Cath Connect#1-3).</p> <p>Disconnect and reconnect the cables</p> <p>Restart the system. If problem persists – contact an authorized MediGuide technician.</p>
16.	Displays turn "black"	HW malfunction causes lack of display	<p>1) Check the power indication on each monitor, and verify that the monitor is turned on. If not – check input cable. If problem persists – contact imaging system vendor technician.</p> <p>2) Verify the video input cables are connected . Restart the system. Contact MediGuide's authorized technician.</p>

Item #	Error	Description	Corrective action
17.	General power failure	All visible indications are not powered – MediGuide Connect, displays, mouse.	<ol style="list-style-type: none"> 1) During a procedure – continue without using MediGuide, as in any other invasive operation. 2) Check with the hospital whether main power to the system has been disabled. 3) Consult an authorized MediGuide technician.
18.	Over-temperature message	One of the devices has reached a temperature above expected limit	<ol style="list-style-type: none"> 1) Shut the system down, and wait for at least 20 minutes. Restart. 2) Verify that the ambient temperature in the cath lab is between 15-27C (for optimal performance) or 10-40C (for decreased performance)
19.	<Table Unit> disconnected	One of the HW peripheral units got disconnected	<ol style="list-style-type: none"> 1) Wait 40 seconds for communication to resume 2) Verify that all cables are securely connected to the MediGuide Connect and MediGuide Cath Connect 3) Restart the system

Item #	Error	Description	Corrective action
			4) Contact MediGuide authorized technician
20.	Acquired cine not accepted by the System	After cine recording, the cine is not added to the cine list. An error message appears indicating that.	1) Ensure the patient has a stable respiration and ECG. 2) Wait for a stable green “M” in the status area. 3) Record the cine, making sure to record for at least 3 seconds.
21.	Acquired cine added to the cine-list with a red “X”. The cine is not automatically played back.	During cine recording an abrupt change in patient’s ECG, respiration or position has occurred, causing a potential inaccuracy in projection on that cine.	1) If possible, it is recommended to record another cine that will be fully accepted. 2) Otherwise, this cine can be used by clicking on it in the cine-list. However, projection of MediGuide data on it may have inferior accuracy.

7.2 MediGuide Patient Reference Troubleshooting

7.2.1 Functional troubleshooting

If after connecting the MediGuide Patient Reference to the MediGuide Connect port marked “**MediGuide Patient Reference 1**” and attaching the MediGuide Patient

Reference into its patch inside the MB, the MediGuide Patient Reference status in the System display Status Area remains **Not Connected**, MediGuide's technician should replace the device to a new one.

If the status remains **Not Connected** after replacing the device contact your **MediGuide** authorized service representative.

7.2.2 MediGuide Respiration Monitor

During MediGuide clinical procedures, the patient respiratory and cardiac related motions are being monitored, and the system compensates for these motions for better accuracy.

MediGuide Respiration Monitor (MRM) is designed to give the System user the ability to monitor the respiration compensation status of the system if insufficient accuracy is observed. If needed, it enables a MediGuide representative to perform corrective actions, during the procedure.

As shown in Figure 7-1, the **MRM** includes the respiration graph, the ECG graph, status information regarding connected MediGuide Enabled devices, and a list of parameters. **The use of this view is intended for St. Jude Medical personnel only.** In this view the current values of the listed parameters, detailing information about patient respiration pattern, patient movements and ECG signal detection quality are displayed. Based on the information in this view, the user\technician can initiate corrective actions, before a procedure starts.



Figure 7-1: MRM

The detailed MRM parameters description is depicted in the following table:

Parameter Name	Parameter Description	Expected Threshold Value	Failure Modes
Number of full function (heart and respiration) learned	The number of motion compensation functions (heart and respiration) learned until the current moment.	N/A	None
Number of active respiration functions	The number of locations along the anatomical structure, in which a respiration motion compensation function was learned.	N/A	None



Parameter Name	Parameter Description	Expected Threshold Value	Failure Modes
Number of active heart functions	The number of locations along the anatomical structure, in which a heart function was learned.	N/A	None
Time from last full learning attempt	The time elapsed from the last learning attempt.	N/A	None
Last full learning attempt quality	The quality of the last motion compensation function. High quality means that there is a good correlation between the MediGuide Patient Reference and MediGuideEnabled Device movements.	> 0.5	None
Last respiration measure failure status	The cause of failure of the motion compensation learning process.	N/A	None
MediGuide Patient Reference motion direction	The main direction of the respiration, observed from the MediGuide Patient Reference signal.	N/A	Failure may indicate an incorrect MediGuide Patient Reference attachment or positioning. Verify MediGuide Patient Reference and patch.

Parameter Name	Parameter Description	Expected Threshold Value	Failure Modes
MediGuide Patient Reference amplitude	The calculated MediGuide Patient Reference amplitude. A minimal amplitude is required to provide a proper MediGuide Patient Reference signal for the motion compensation process.	> 0.04 cm	Failure may indicate an incorrect MediGuide Patient Reference attachment or positioning. Verify MediGuide Patient Reference and patch.
MediGuide Patient Reference noise	The calculated MediGuide Patient Reference noise. A maximal noise level is allowed to provide a proper MediGuide Patient Reference signal for the motion compensation process.	< 0.1 cm	Failure may indicate an incorrect MediGuide Patient Reference attachment or positioning. Verify MediGuide Patient Reference and patch.
Angle between MediGuide Patient Reference-Z and the respiration motion direction	The angle between the Z-axis of the MediGuide Patient Reference (up-down relative to the table) to the main respiration direction.	< 60 degrees	Failure may indicate an incorrect MediGuide Patient Reference positioning. Verify MediGuide Patient Reference and patch.
ECG HR [BPM]	The current heart rate of the patient.	30÷300 bpm	Consistent HR outside these limits will prohibit correct function of the System
ECG stability	The difference between two consecutive RR intervals.	< 60%	Continuous ECG instability may harm the accuracy of MediGuide device projection on previously acquired images



Parameter Name	Parameter Description	Expected Threshold Value	Failure Modes
ECG detection rate	The detection rate of R-waves of the ECG signal.	> 95%	Low detection rate may harm the accuracy of MediGuide device projection on previously acquired images
Last respiration period	The last period time of the respiration between two consecutive minima.	< 6 sec	Consistently slower respiration may harm the accuracy of MediGuide device projection on previously acquired images
Error Estimation	Estimation of the expected average error [mm] when respiration compensation is active.	< 0.5 mm	None
MediGuide Patient Reference trend	Information of the MediGuide Patient Reference signal's trend.	< 0.2 cm	None

Two examples of good signal and poor respiration signal, indicating extensive patient movements, are shown below in Figure 7-2 and Figure 7-3 respectively.



Figure 7-2: Example of a Good Respiration Signal



Figure 7-3: Example of a poor respiration signal, indicating extensive patient movements

8 Safety and Compliance Standards

The MediGuide™ System, in conjunction with any MediGuide Enabled™ device meets the safety and compliance standards and requirements listed below.

General Safety

EN 60601-1 (+amnd.1, 2)	General Safety requirements for Medical Electrical Equipment
EN 60601-1-1	General Safety requirements for Medical Electrical Systems
EN 60601-1-4	Programmable Electrical Medical Systems

Risk Management

EN ISO 14971:2007	Medical devices - Application of risk management to medical devices.
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Magnetic Field Safety

ICNIRP Guidelines 1998	Guidelines for limiting exposure to time-varying electric, magnetic and electromagnetic fields (up to 300 GHz)
ANSI/IEEE C95.1-1999	Standard for safety levels with respect to human exposure to radio-frequency electromagnetic fields, 3 kHz to 300 GHz.
ACGHI (2004 edition)	Threshold limit values for chemical substances and physical agents.

EMC Compliance

EN 60601-1-2	Electromagnetic Compatibility - Requirements and Tests
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9 Emissions Declaration

9.1 Electromagnetic Emissions – Declarations

Table 9-1: Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The MediGuide™ Technology Model MB0753B-00 is intended for use in the electromagnetic environment specified below. The customer or the user of the MediGuide™ Technology Generator should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The MediGuide™ Technology Model MB0753B-00 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The MediGuide™ Technology Model MB0753B-00 is suitable for use in all establishments directly connected to the public low-voltage power supply network.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 9-2: Electromagnetic Immunity Declaration I

Guidance and manufacturer's declaration – electromagnetic immunity			
MediGuide™ Technology System Model MB0753B-00 is intended for use in the electromagnetic environment specified below. The customer or the user of the MediGuide™ Technology Model MB0753B-00 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air Please see report MEDEMC 20981, page 31	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines Please see report MEDEMC 19686, page 84 to 87	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode Please see report MEDEMC 19686, page 93 to 97	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s Please see report MEDEMC 19686, page 112 to 117	Mains power quality should be that of a typical commercial or hospital environment. Continued operation, during power mains interruptions, is not required for MediGuide™ Technology Model MB0753B-00. After AC mains restoration the MediGuide™ Technology System returned to normal operation after an operator intervention.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m in X,Y,Z Please see report MEDEMC 19686, page 111	The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE : U_T is the a.c. mains voltage prior to application of the test level.			

Table 9-3: Electromagnetic Immunity Declaration II

Guidance and manufacturer's declaration – electromagnetic immunity			
The MediGuide™ Technology Model MB 0753B-00 is intended for use in the electromagnetic environment specified below. The customer or the user of the MediGuide™ Technology System Model MB0753B-00 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conduct RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	Not applicable [E ₁] V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the MediGuide™ Technology Model MB0753B-00 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Field strengths from mixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MediGuide™ Technology Generator is used exceeds the applicable RF compliance level above, the MediGuide™ Technology Model MB0753B-00 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MediGuide™ Technology Generator.			
^b Over the frequency range 150 kHz, field strengths should be less than [V ₁] V/m.			

5 DESIGN CONTROL INFORMATION

Special considerations have been taken in implementing the changes in the modified MediGuide Technology system for the purpose of maintaining its safe and reliable performance.

The incorporated design control and risk analysis methods, used to assess the impact of the modifications, are summarized below. The Risk Analysis method used to (b)(4)

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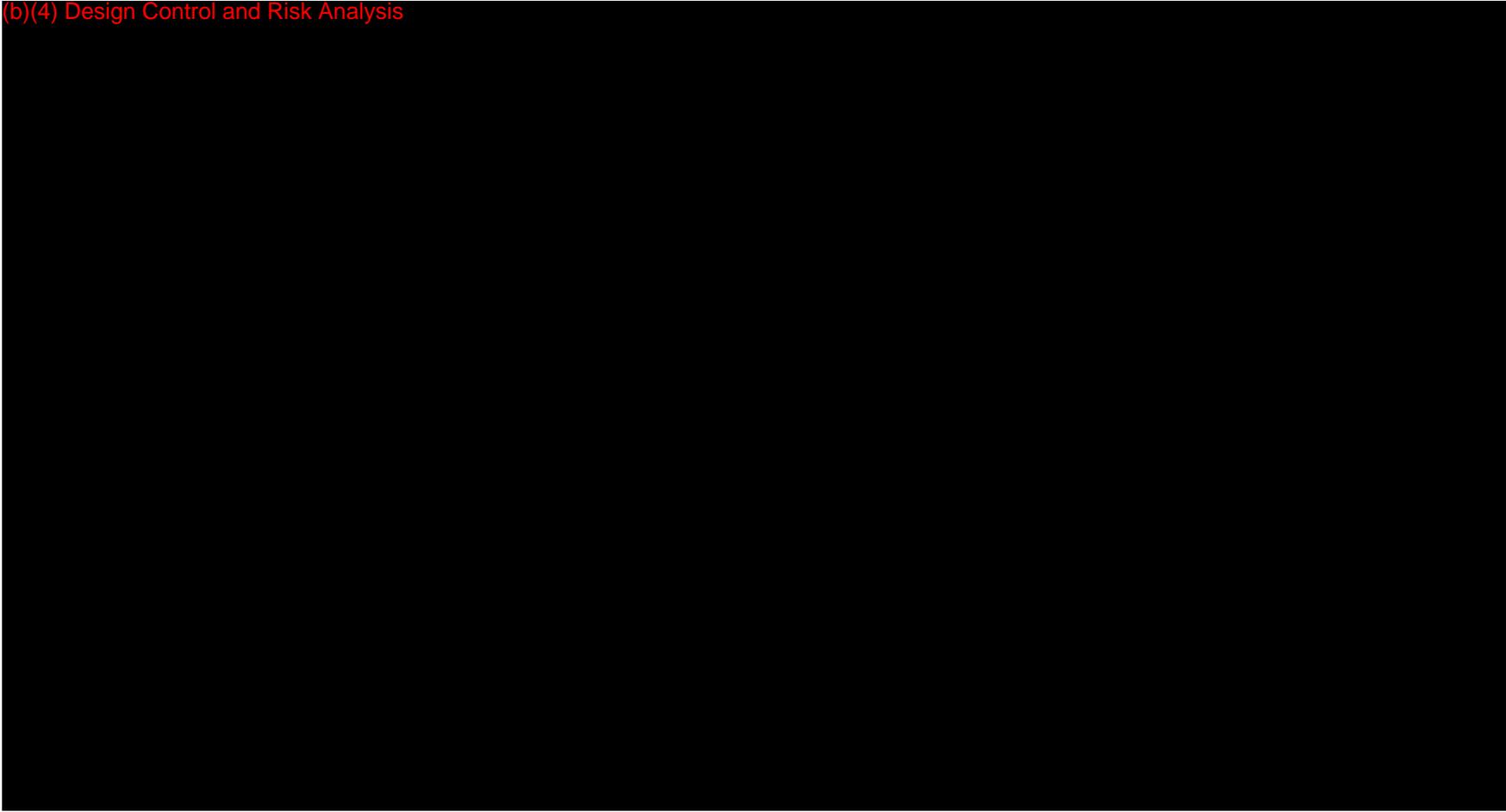
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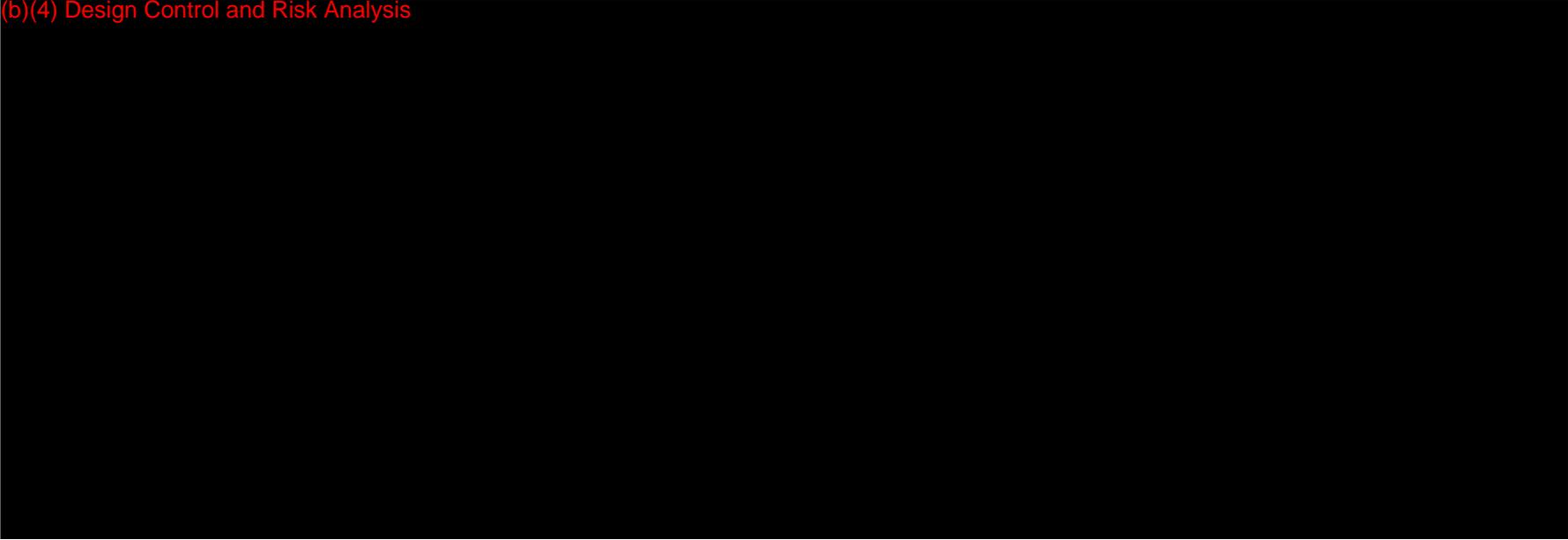
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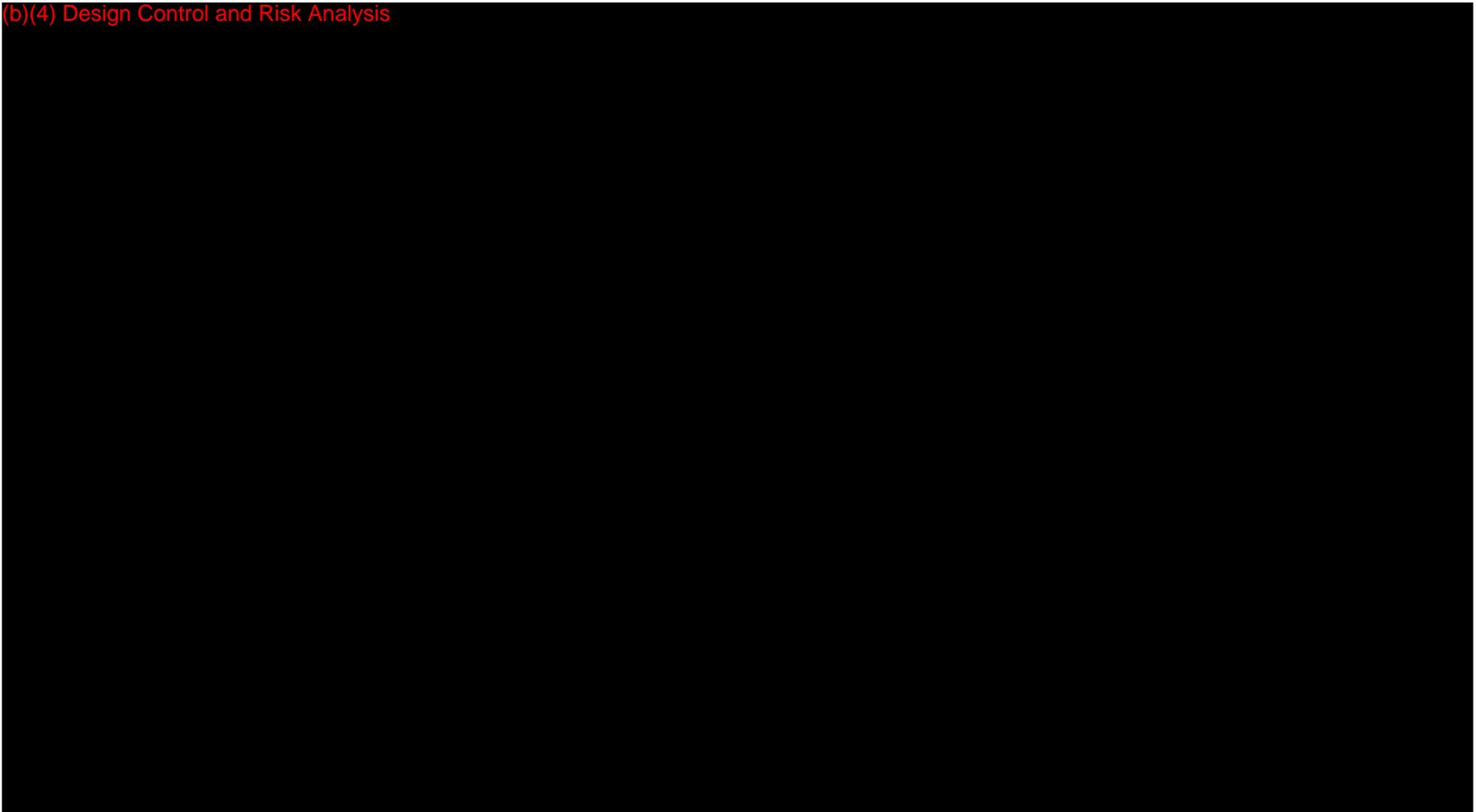
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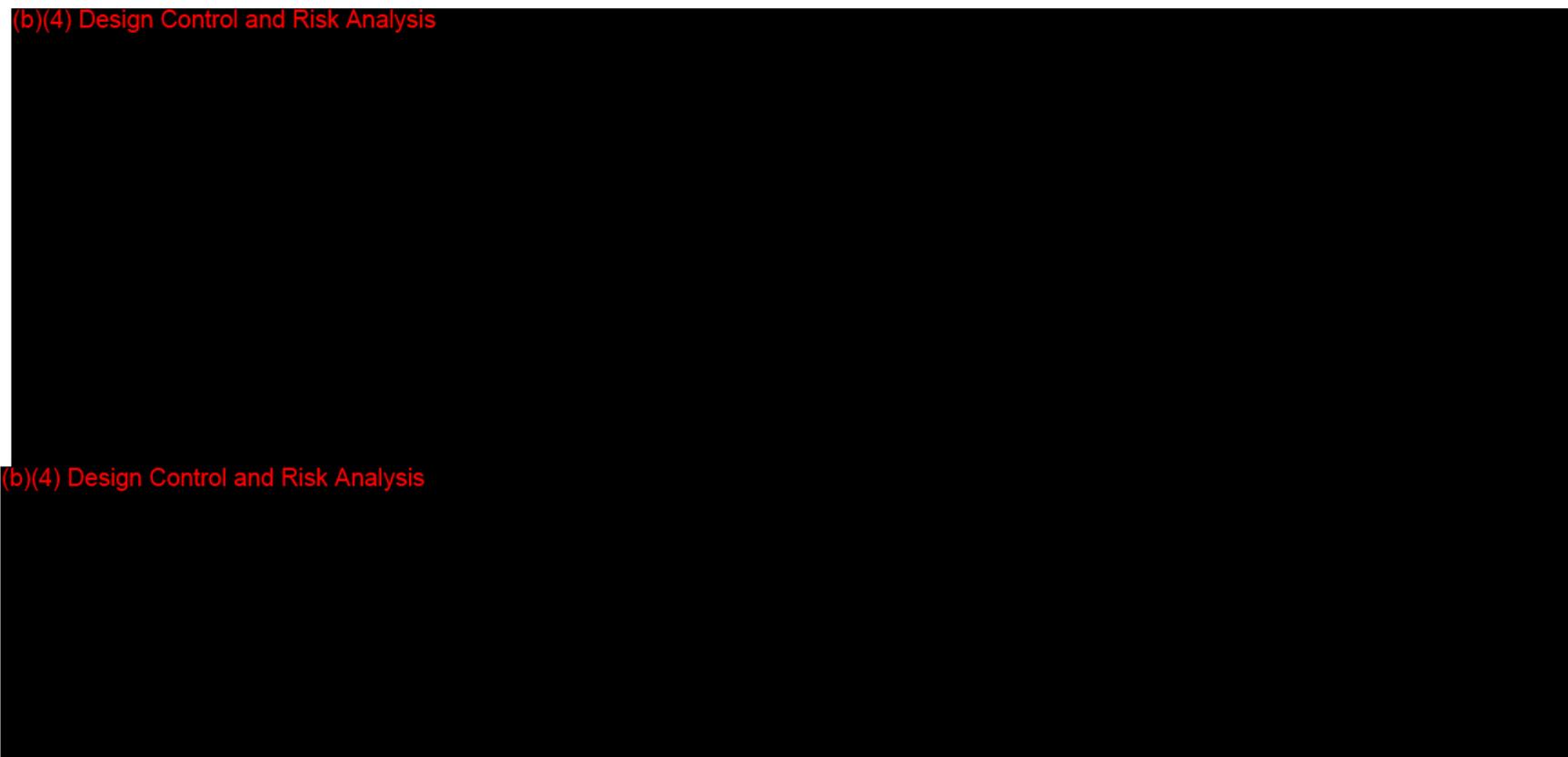
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(b)(4) Design Control and Risk Analysis



(b)(4) Design Control and Risk Analysis

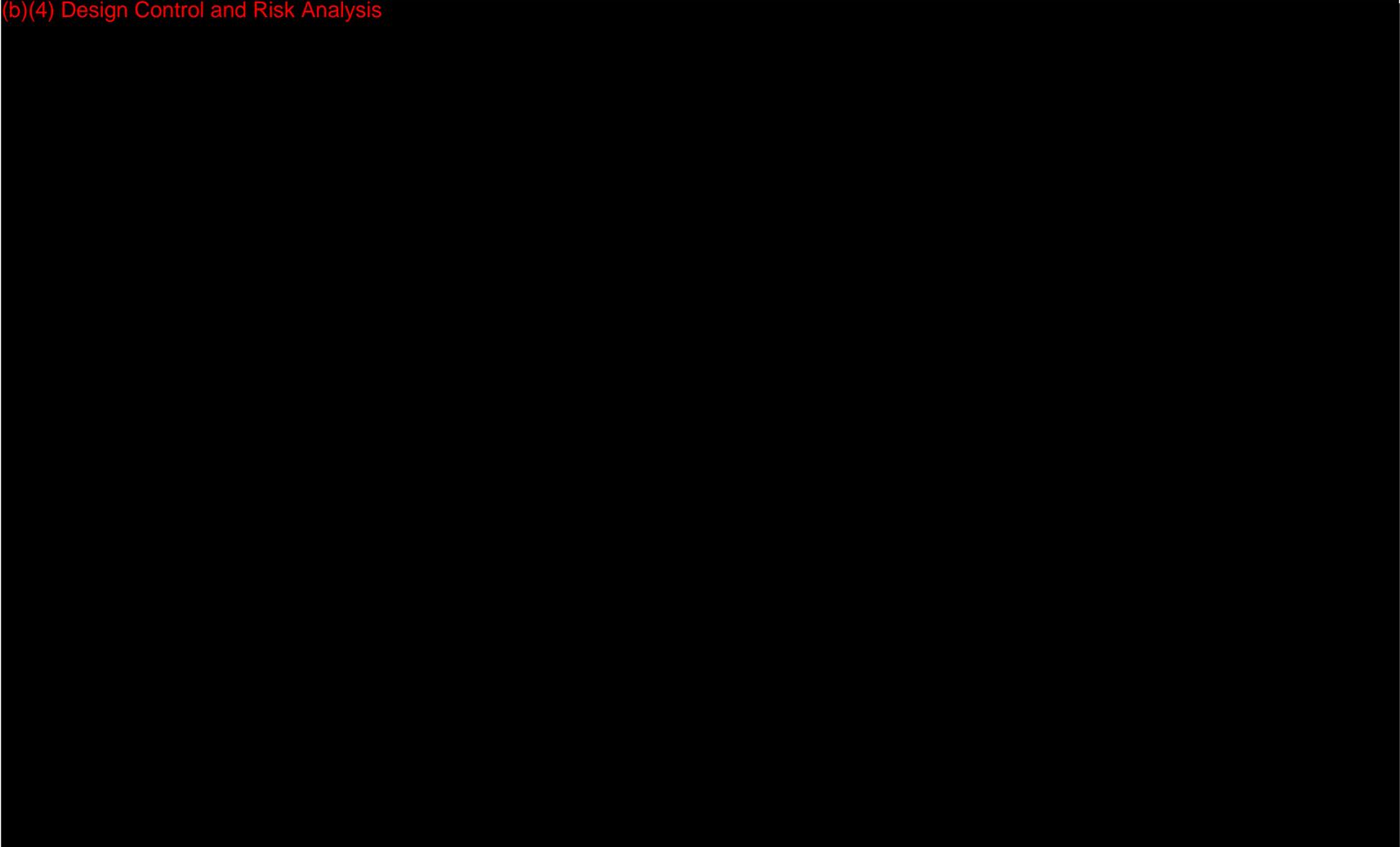


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(b)(4) Design Control and Risk Analysis



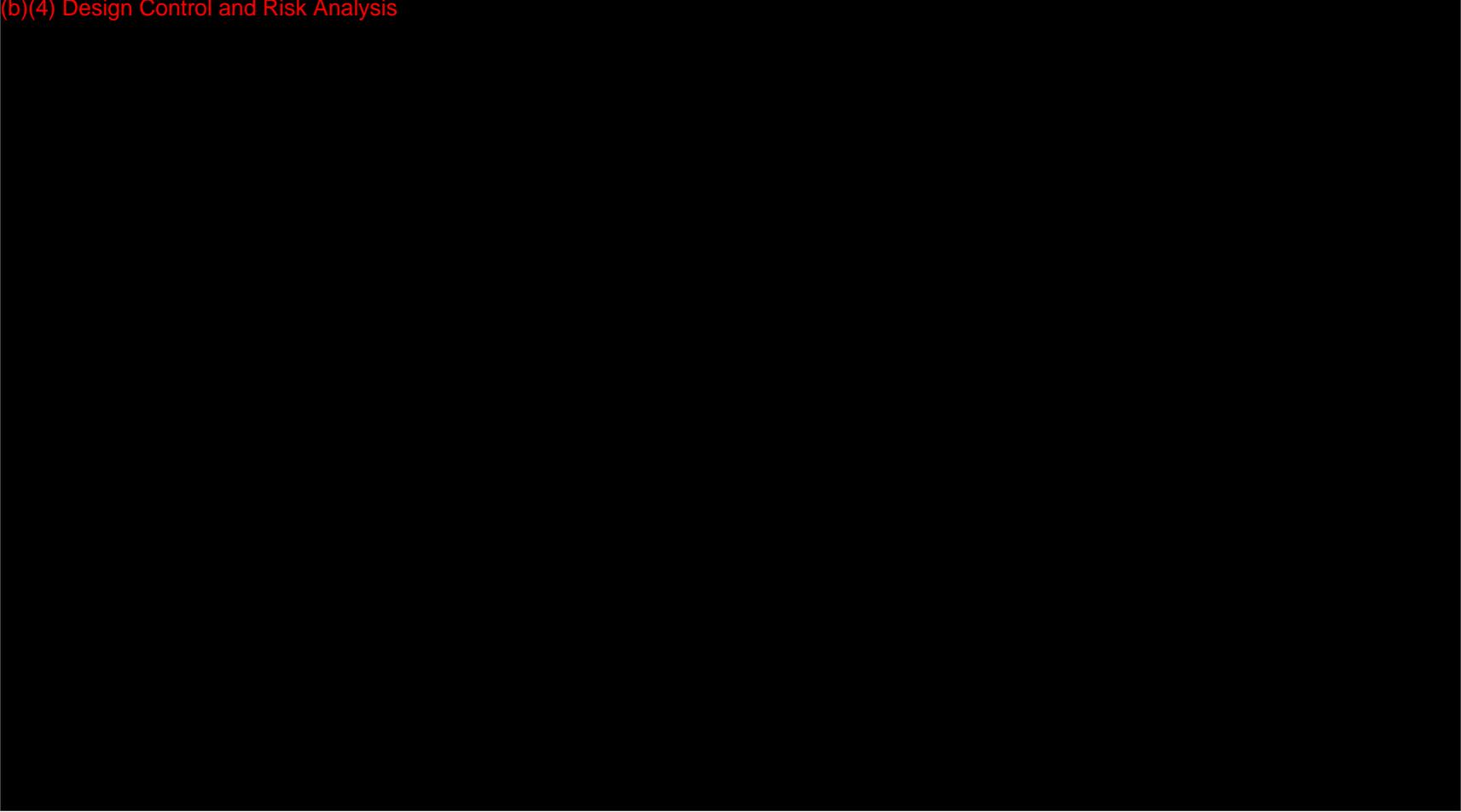
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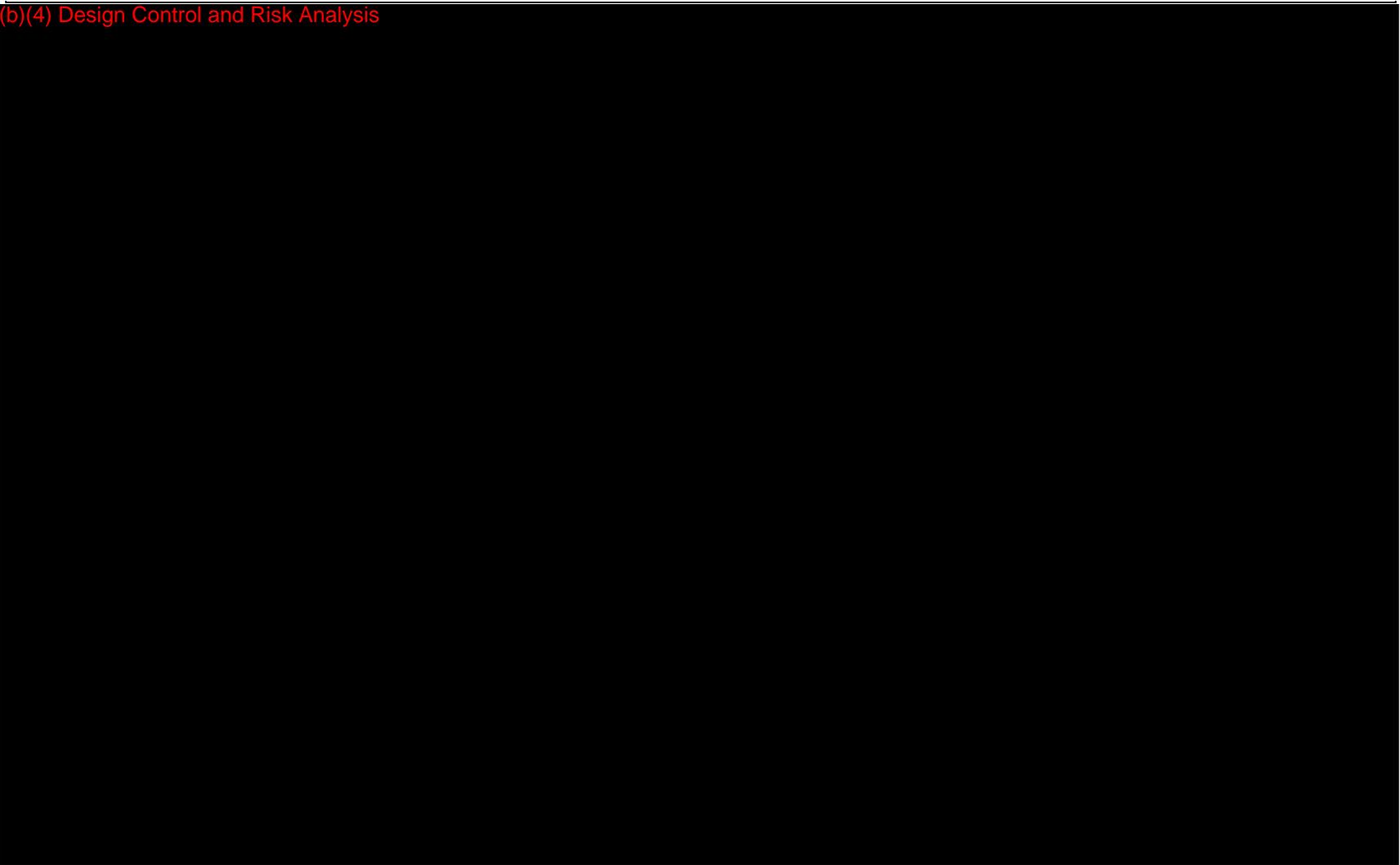
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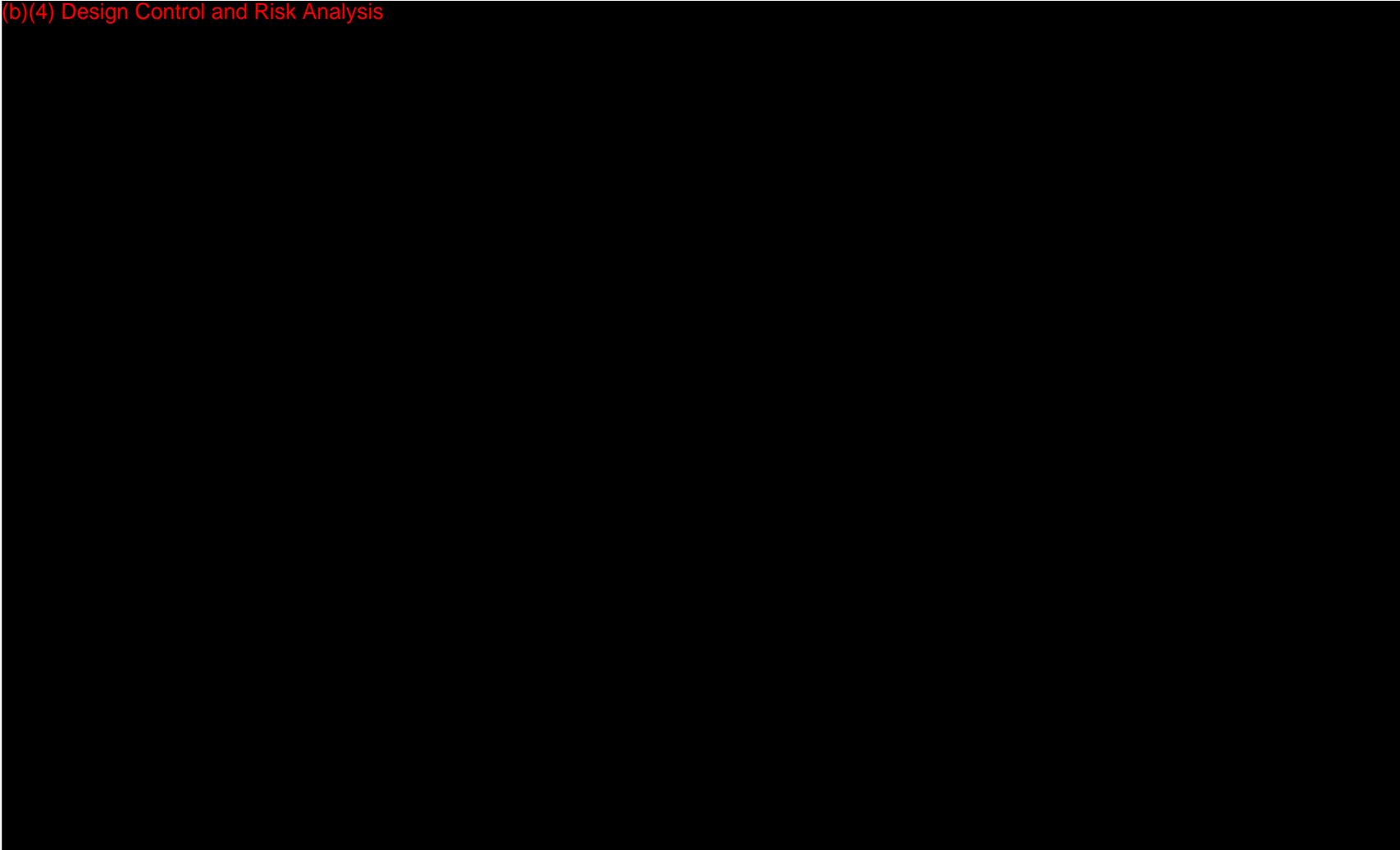
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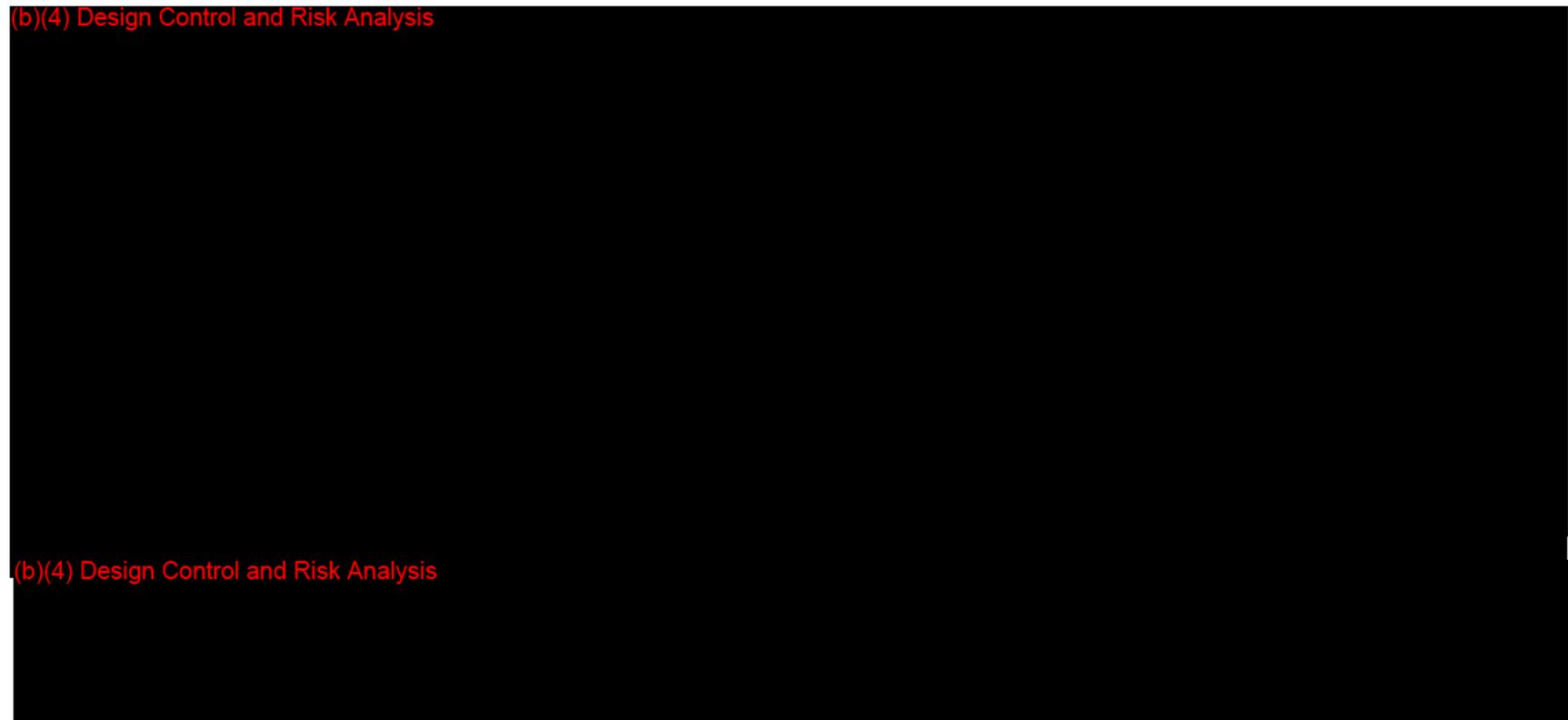
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(b)(4) Design Control and Risk Analysis



(b)(4) Design Control and Risk Analysis



(b)(4) Design Control and Risk Analysis

Conclusion:

Comprehensive design validation processes, performed as a result of this risk analysis assessment, demonstrate that the modified MediGuide Technology system meets its specifications and its safe and reliable performance are maintained.

ATTACHMENT TO SECTION 5

5-1 Declaration of Conformity with Design Controls and Manufacturing Facility

5-2 Bench Testing

ATTACHMENT 5-1

Declaration of Conformity with Design Controls and Manufacturing Facility

DECLARATION OF CONFORMITY TO DESIGN CONTROLS

To the best of my knowledge, the verification activities for The **MediGuide Technology System**, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

(b)(6)

Signature

(b)(6)

Quality Assurance Director
St Jude Medical
MediGuide Navigation Systems

January 25 2012

Date

Manufacturing Facility

The manufacturing facility, St Jude Medical – MediGuide Navigation Systems, is in conformance with the design control requirements as specified in 21 C.F.R. § 820.30 and the records are available for review.

(b)(6)

Signature

(b)(6)

Quality Assurance Director
St Jude Medical
MediGuide Navigation Systems

January 25 2012

Date

ATTACHMENT 5-2

Bench Testing

Bench Testing

(b)(4) Testing

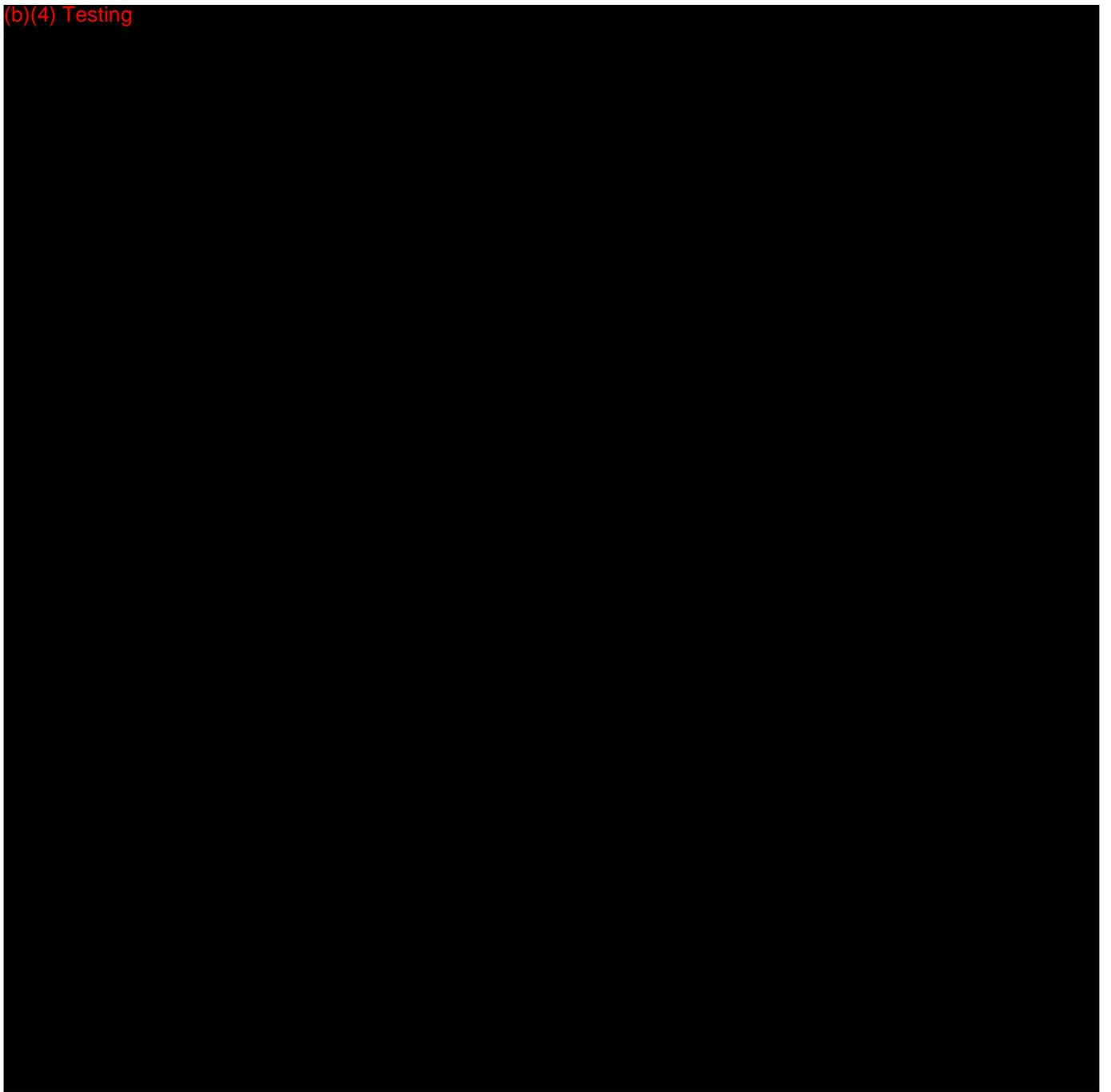
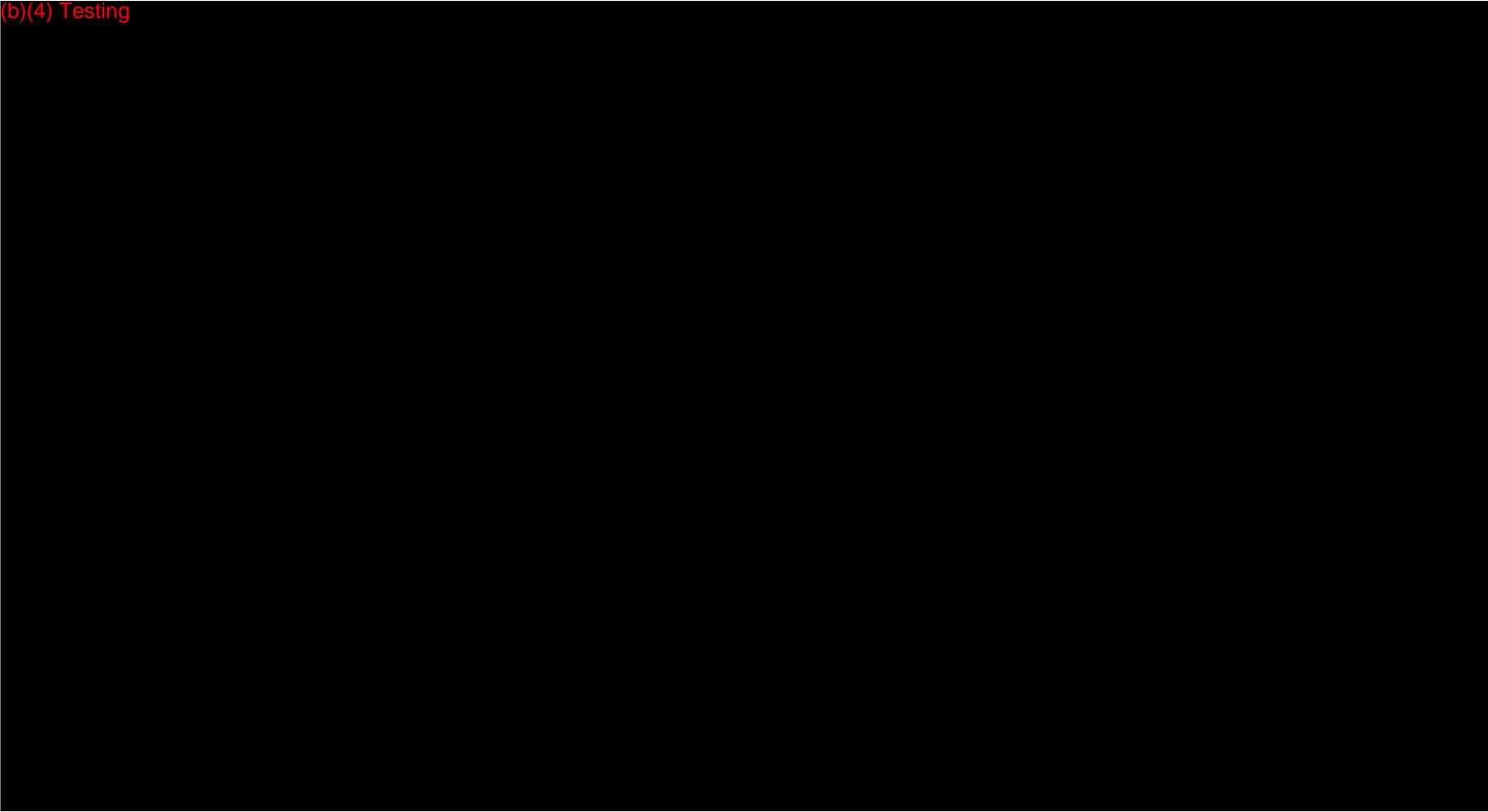
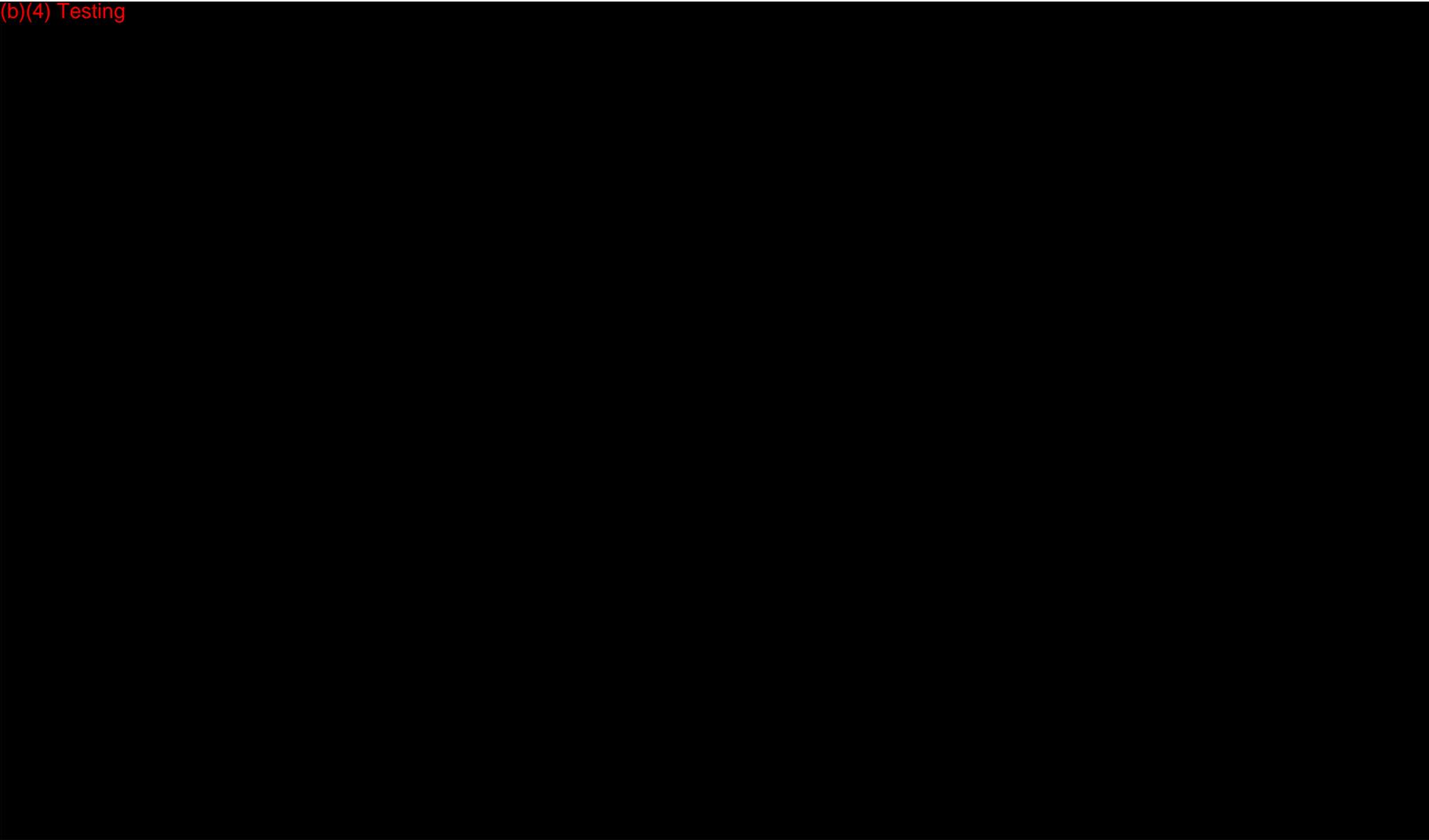


Table 1. Bench tests performed with the modified MediGuide Technology system.

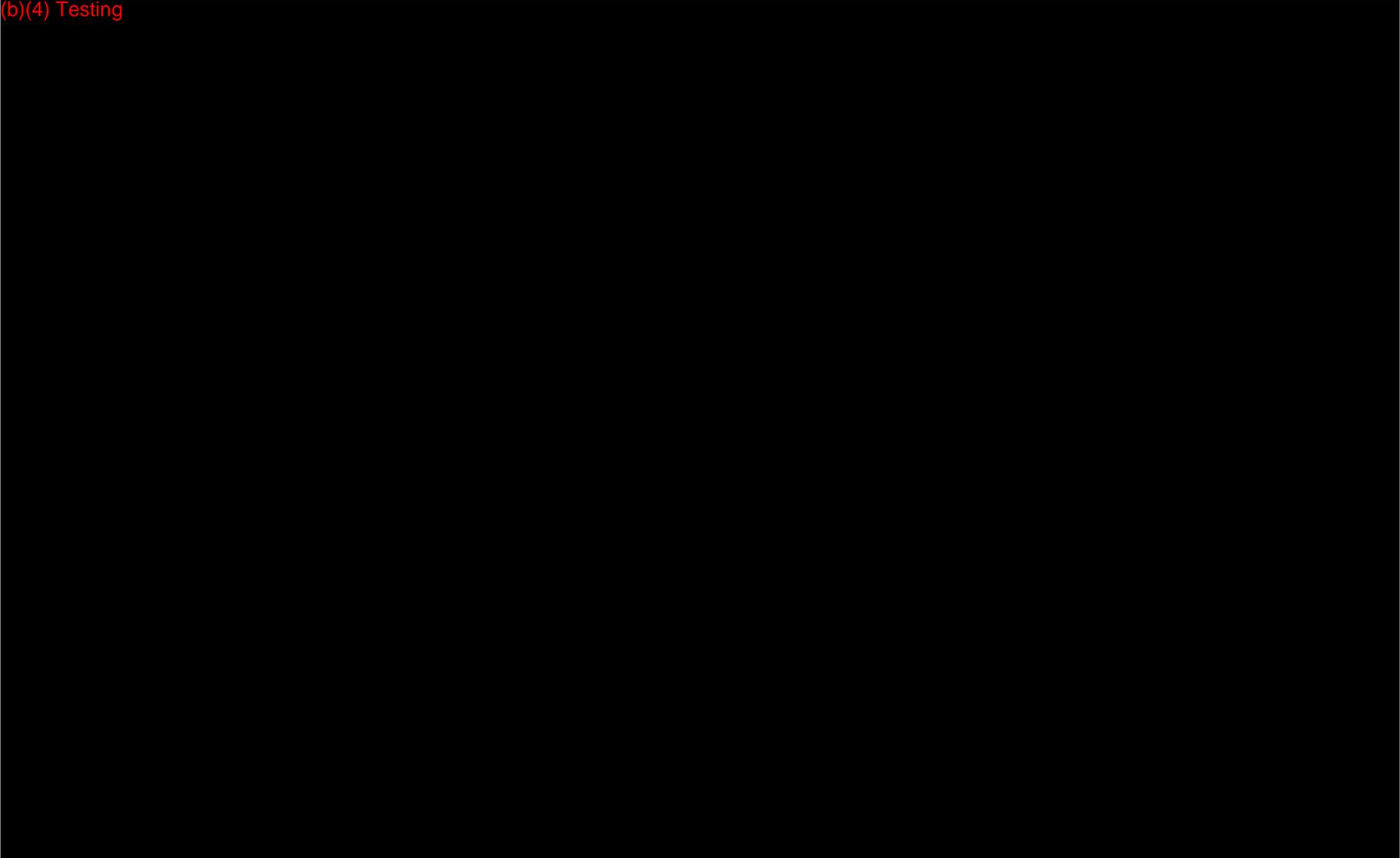
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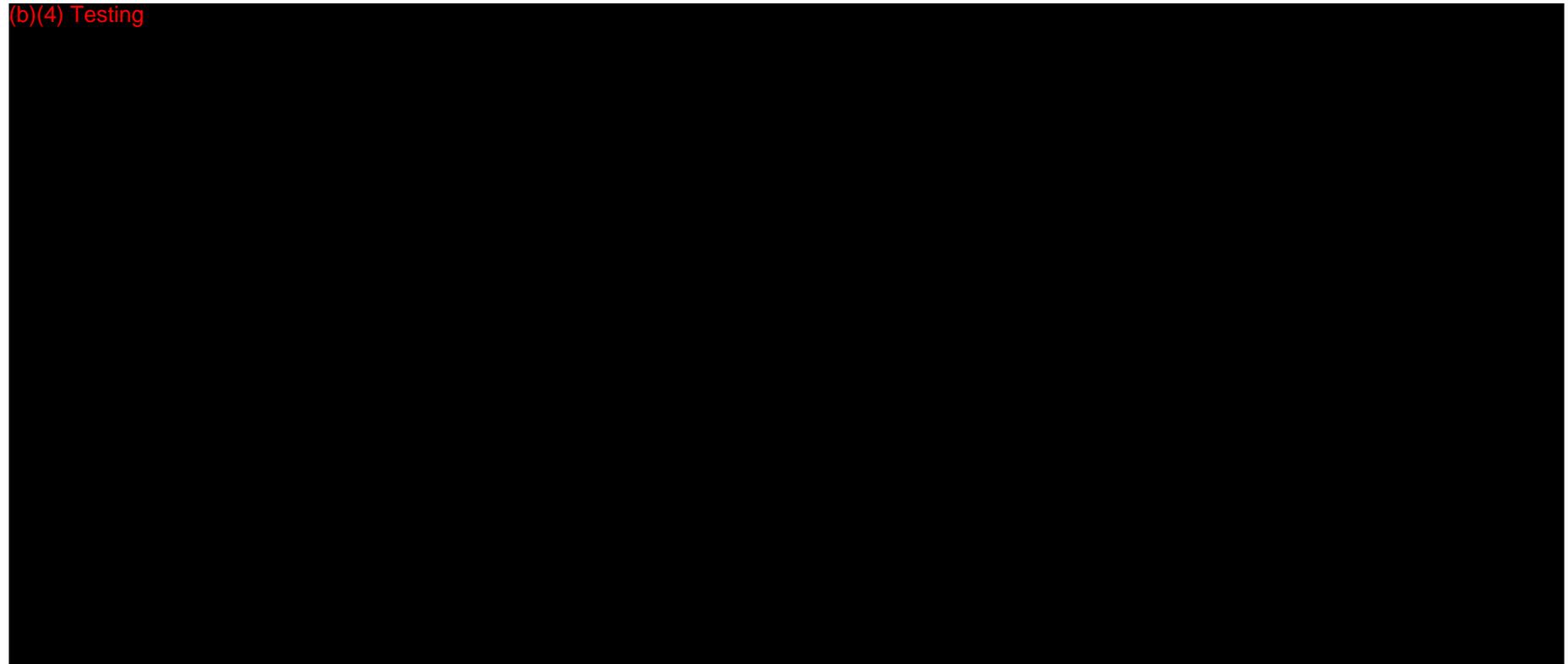
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6 **BIOCOMPATIBILITY**

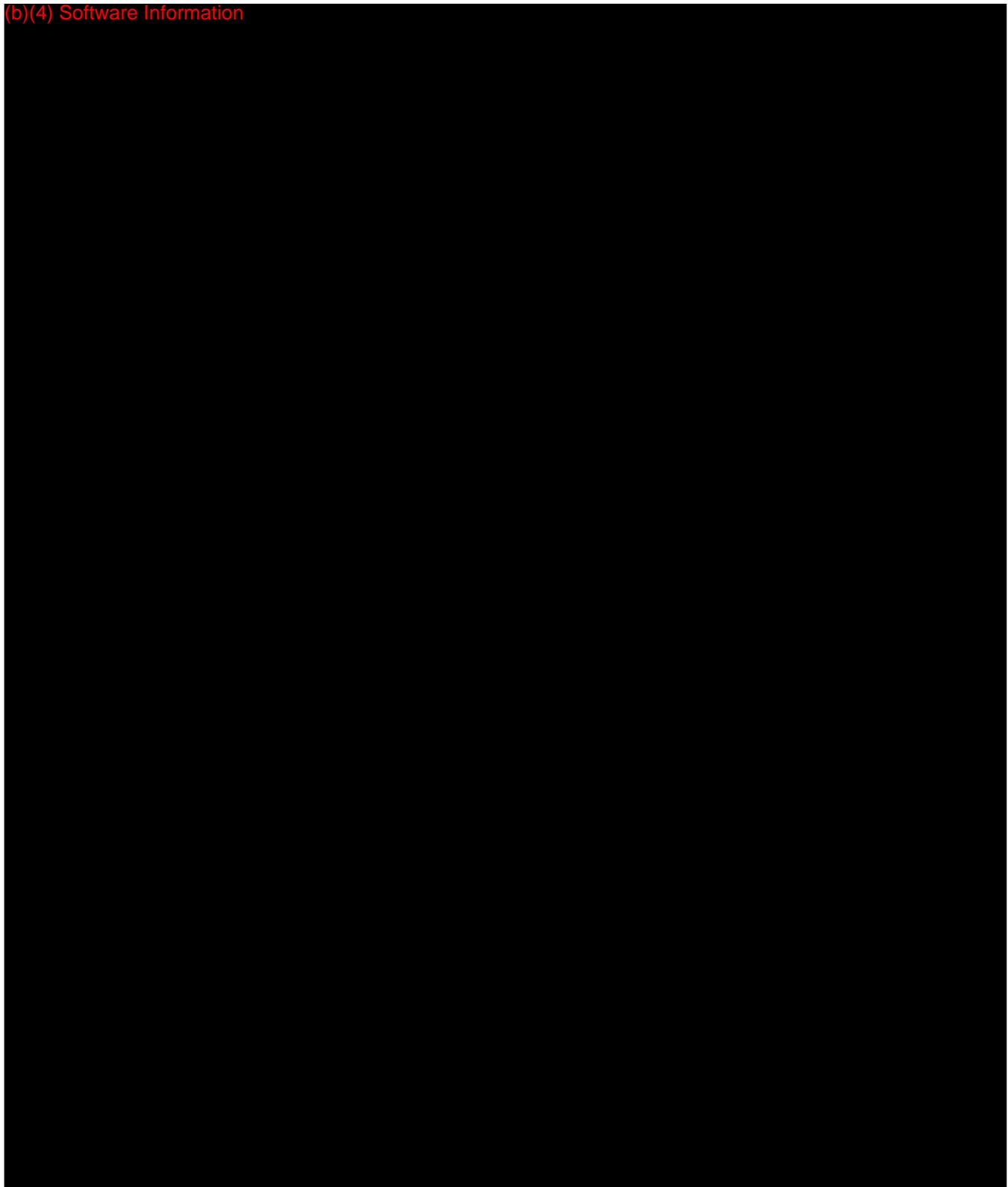
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7 **STERILIZATION AND SHELF LIFE**

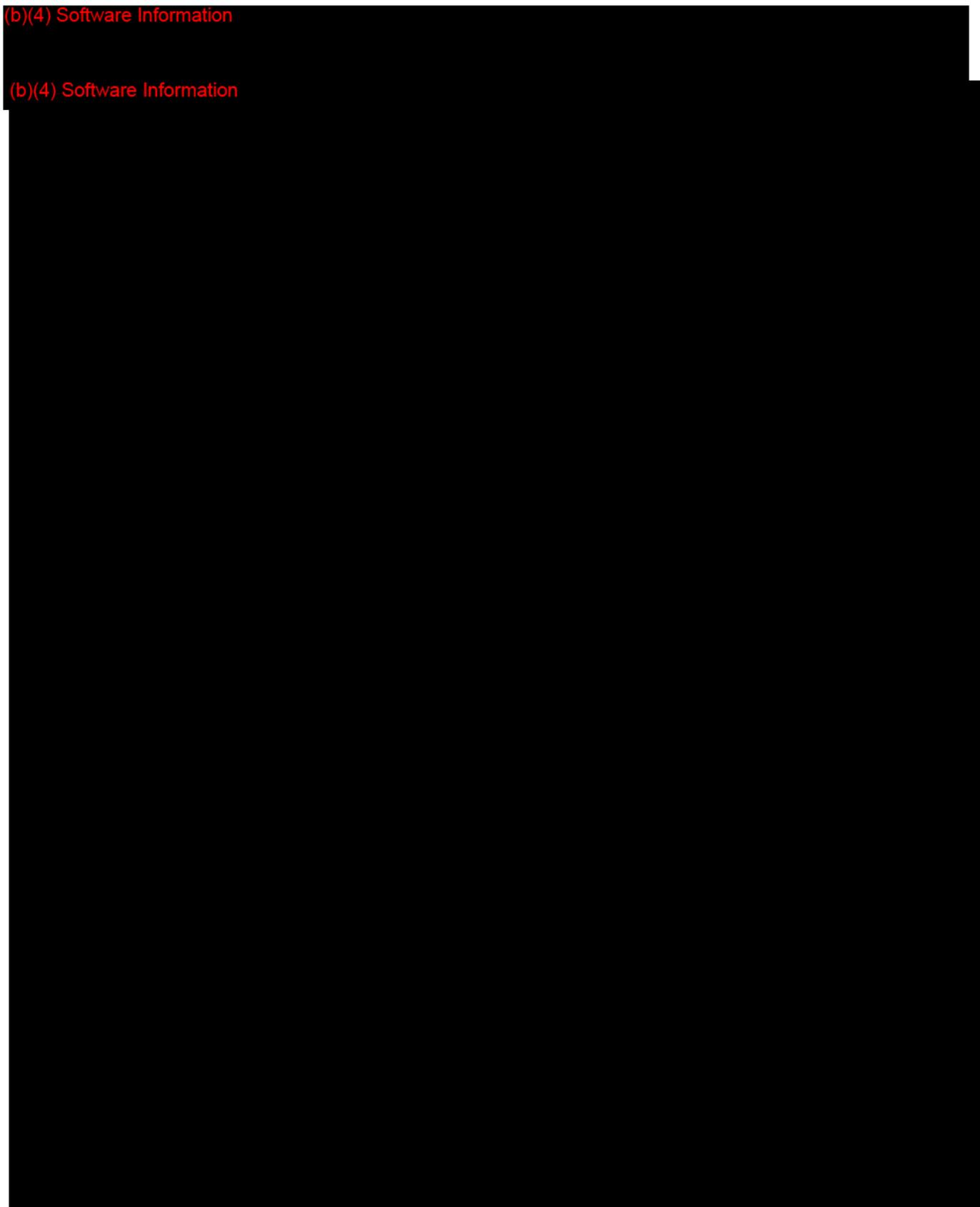
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8 **SOFTWARE**

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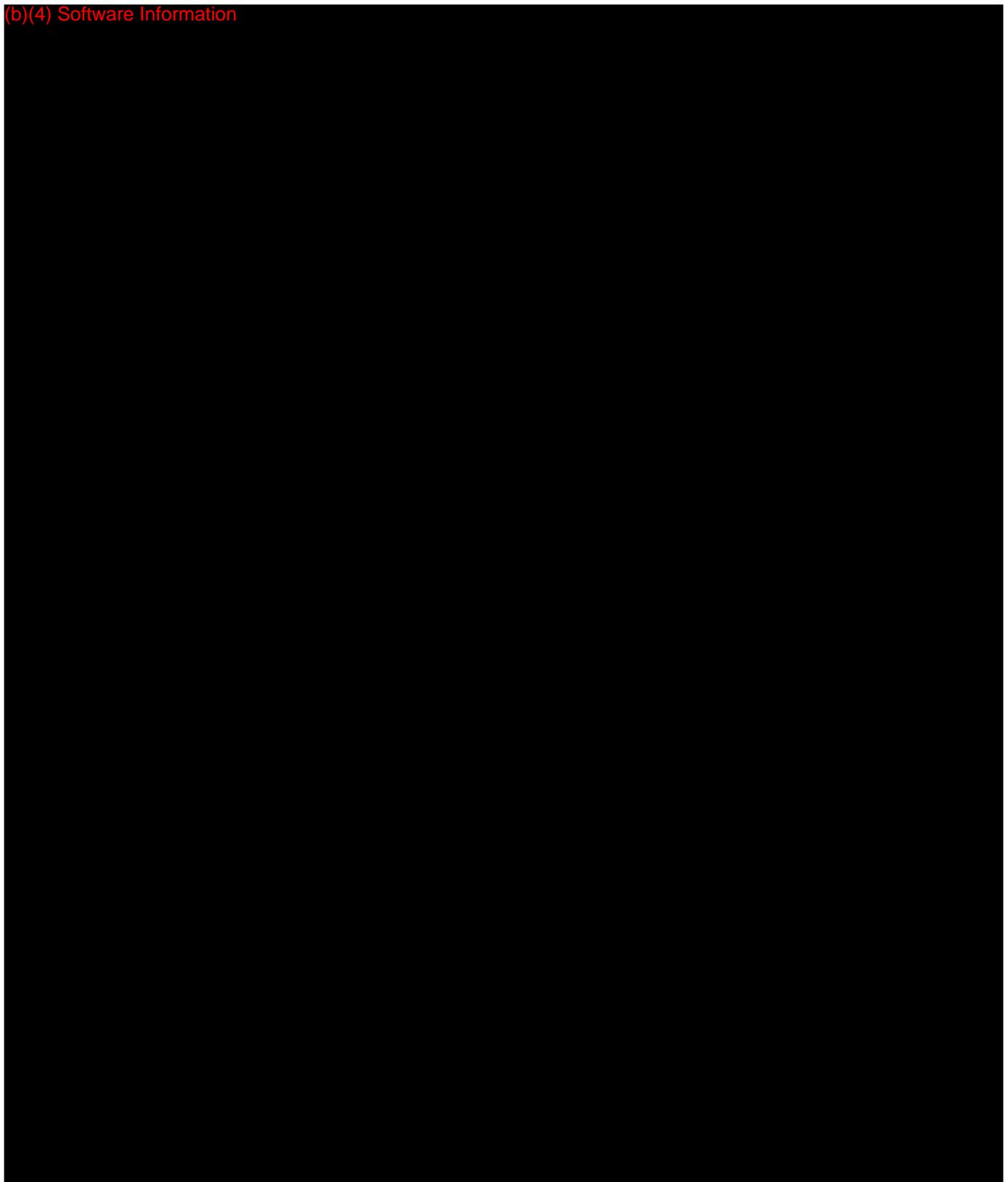


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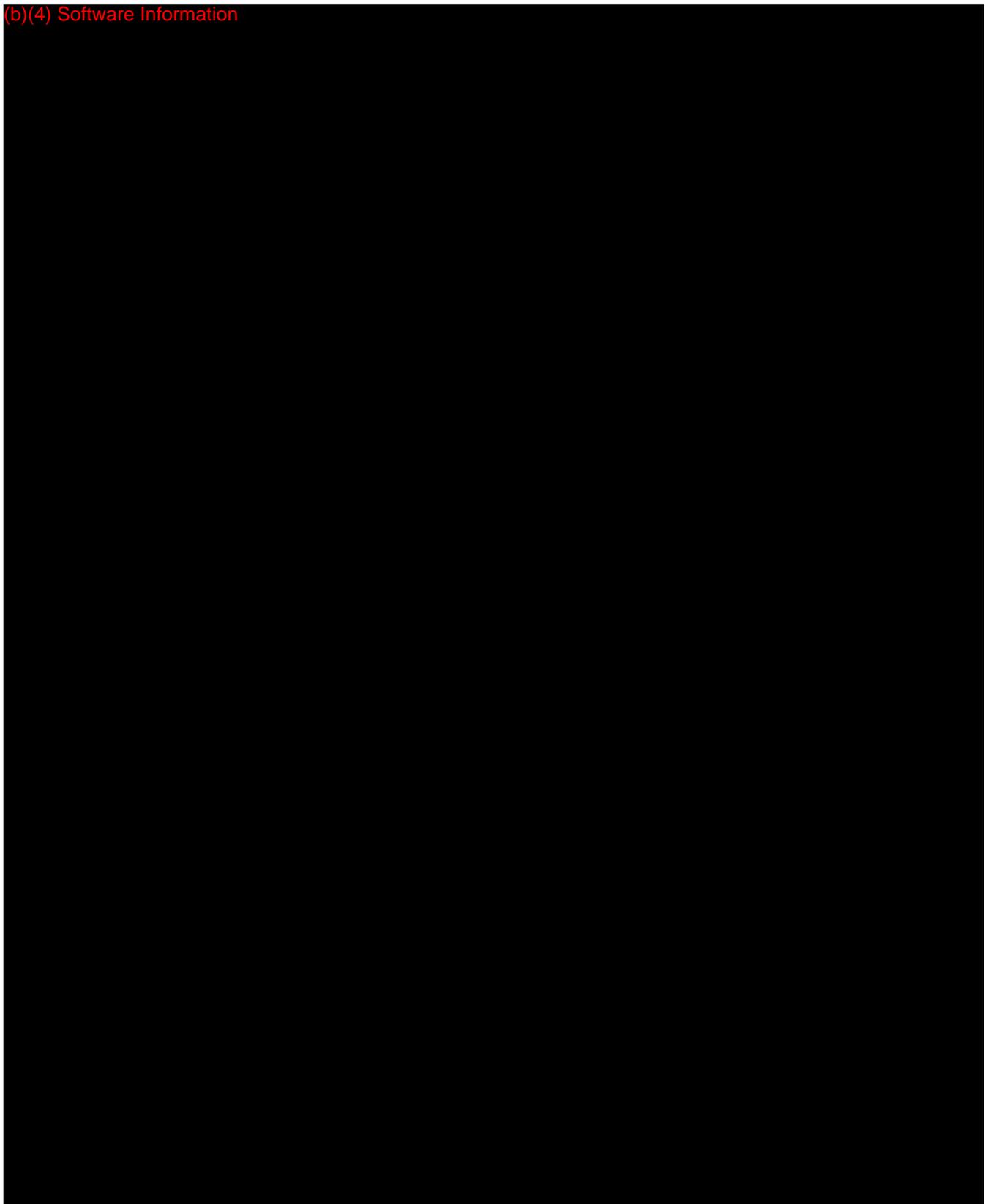


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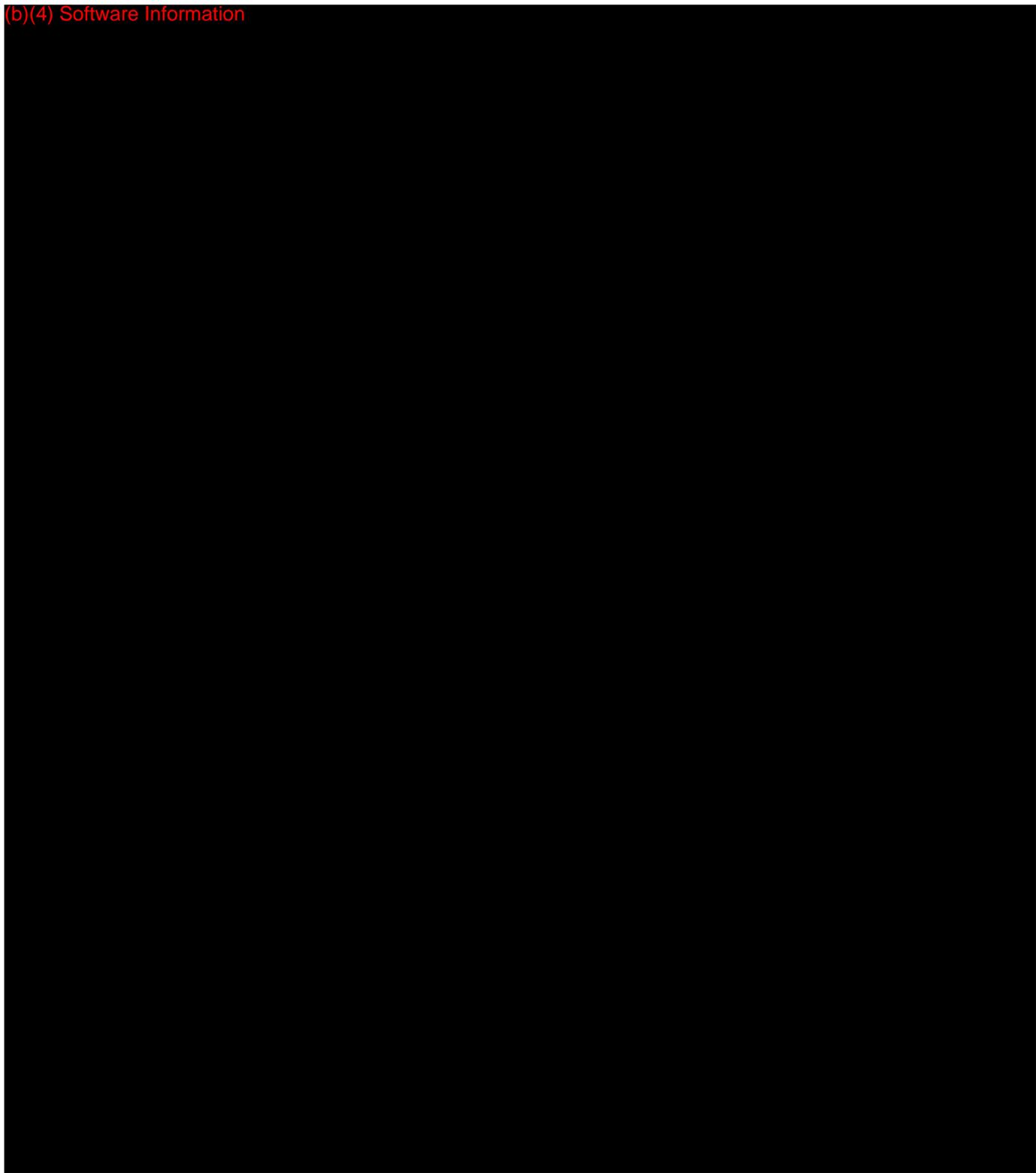
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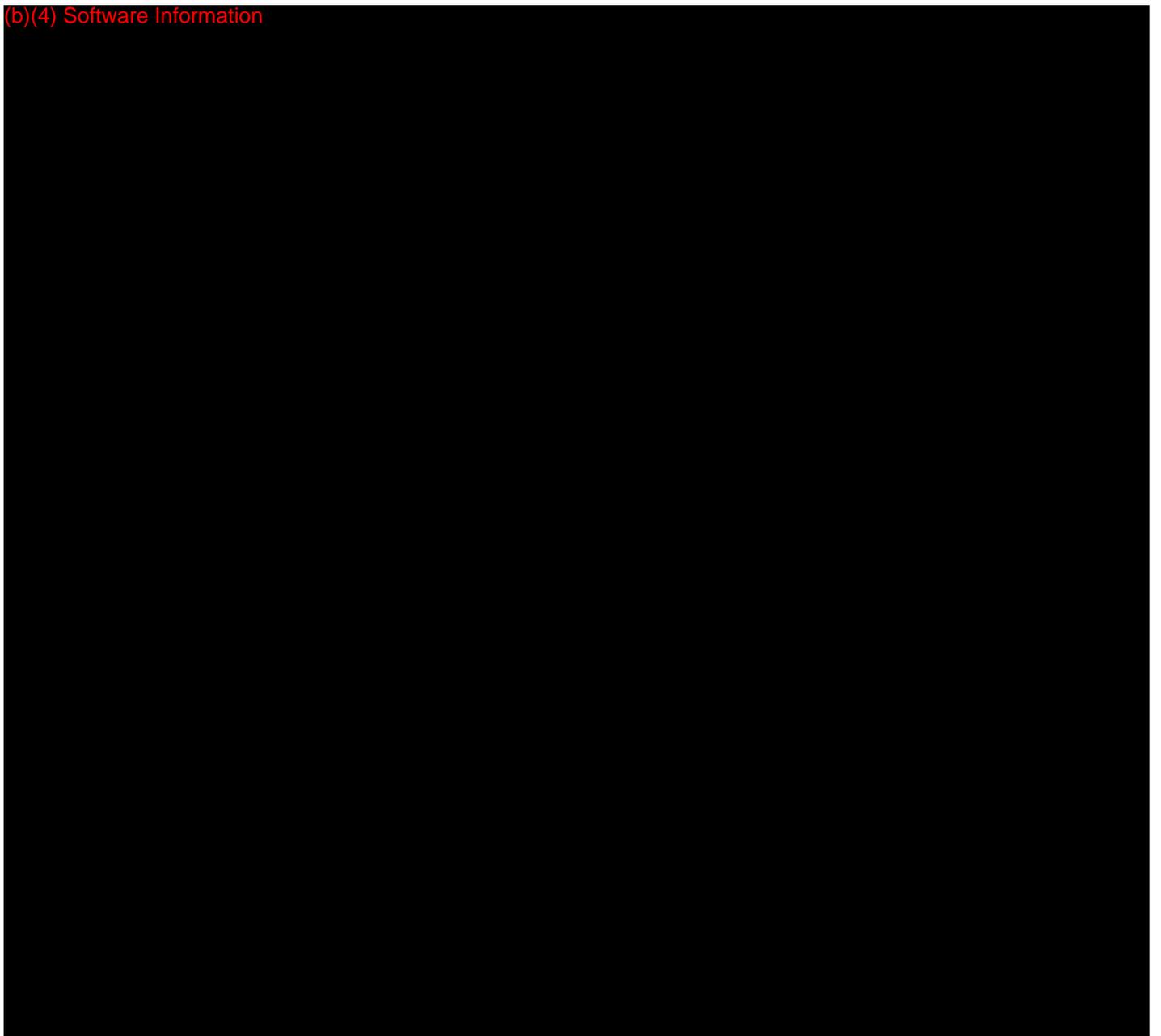
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ATTACHMENTS TO SECTION 8

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- 8-3 **Software** (b)(4) Software Information
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- 8-5 **Software** (b)(4) Software Information
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ATTACHMENT 8-1

Software (b)(4) Software Information

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FCTN	Title	Name	Signature	Date	ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>	St. Jude Medical MediGuide Navigation Systems Advanced Technology Center P.O.B 15003, Haifa 31053, Israel								
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	QA Dir	(b)(6)	(b)(6)	30 Jan 2012										
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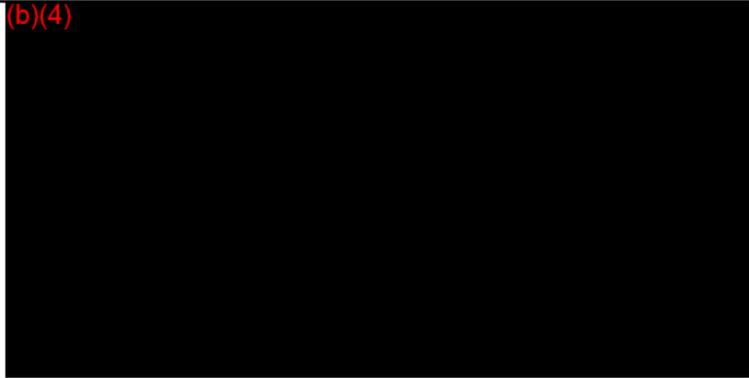
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FIGURE 1
FIGURE 2
FIGURE 3



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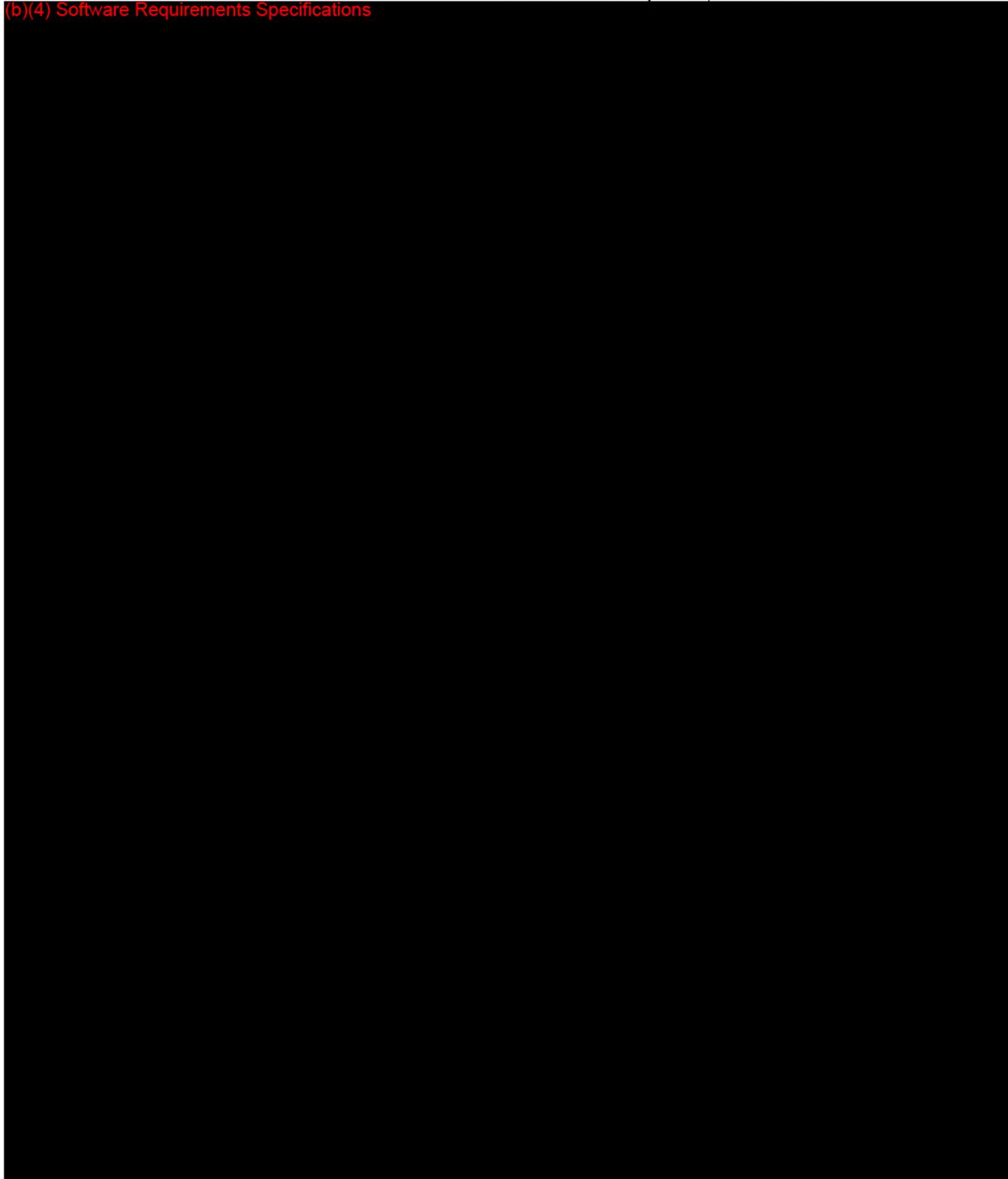




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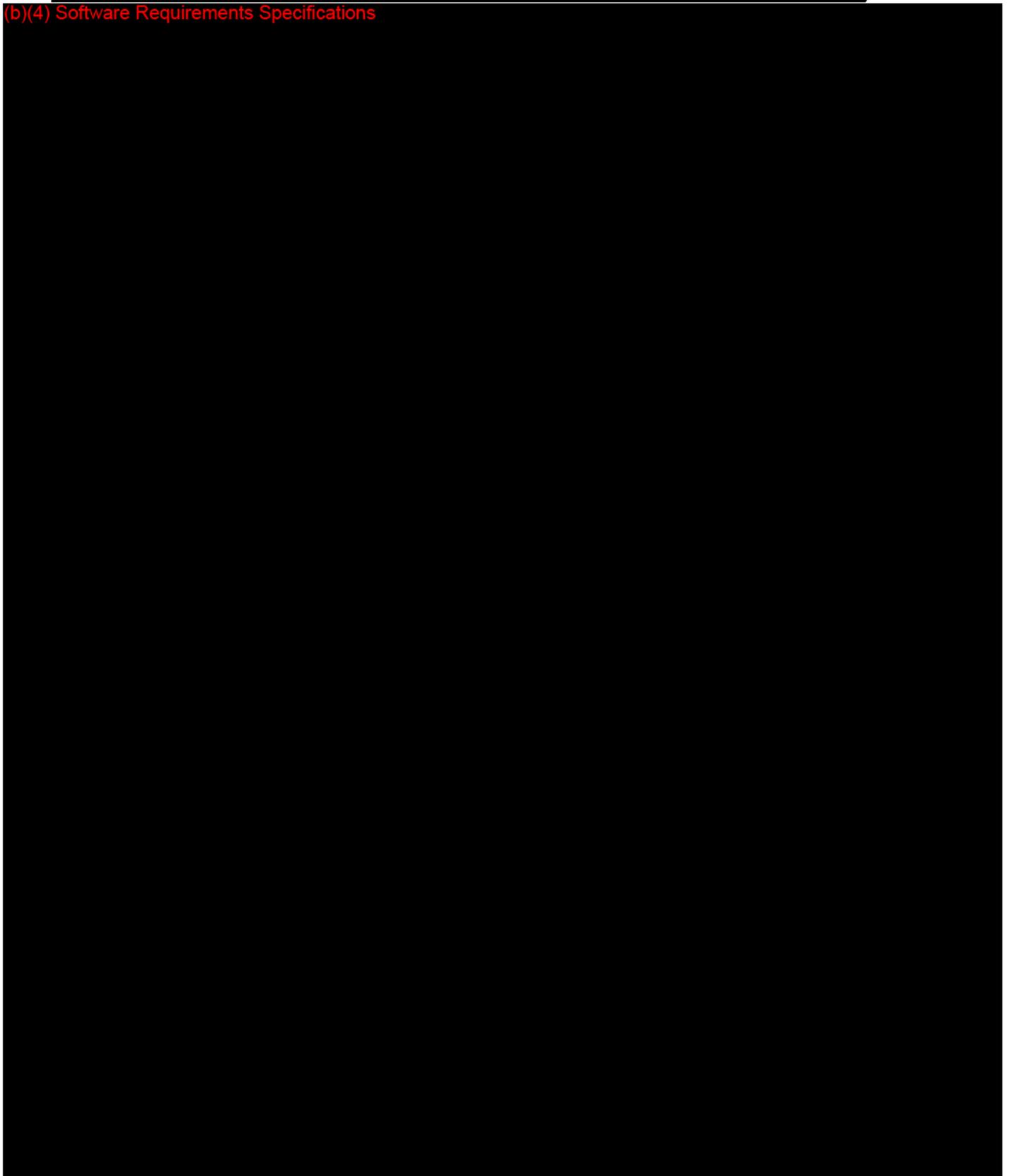




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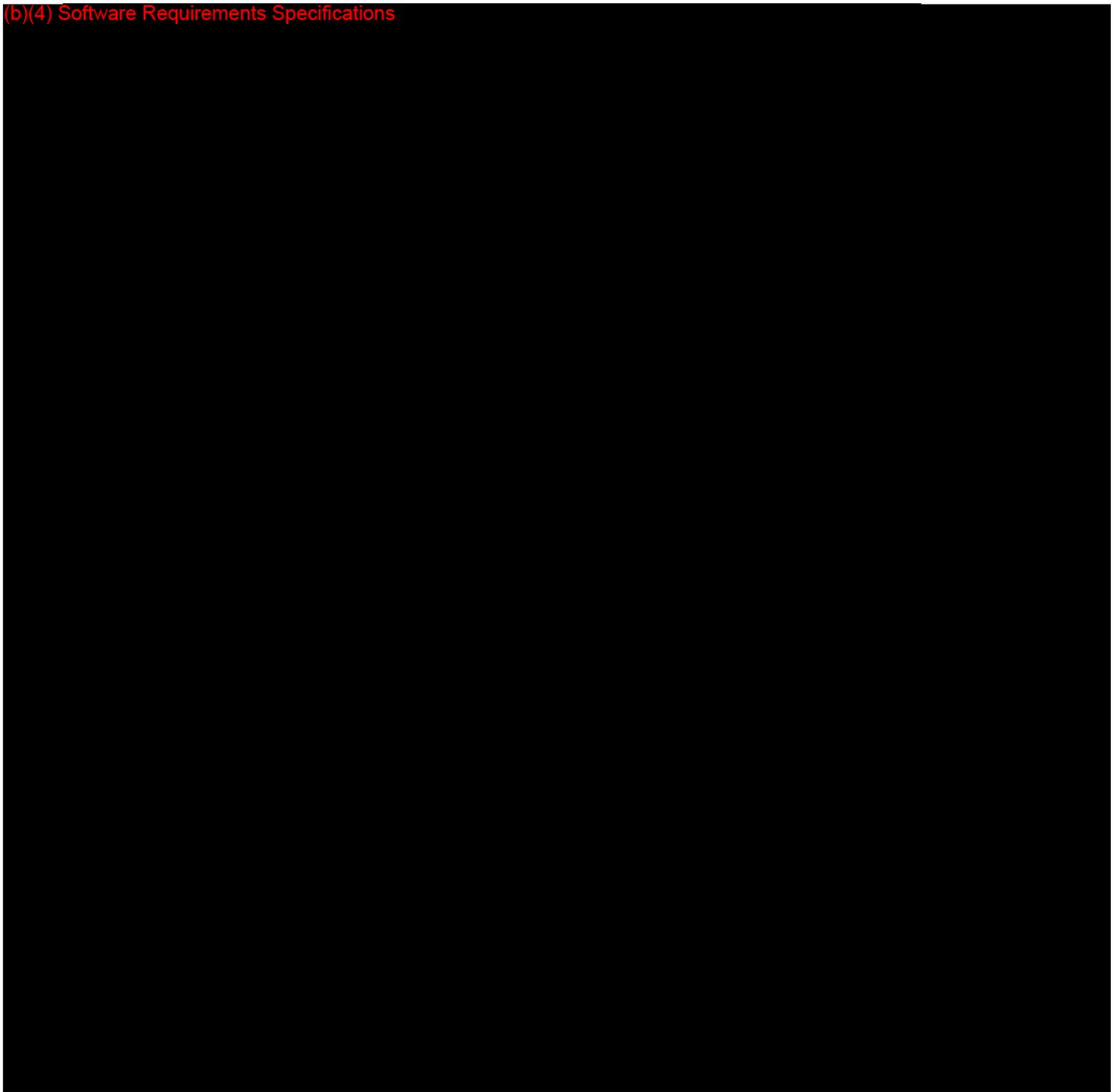
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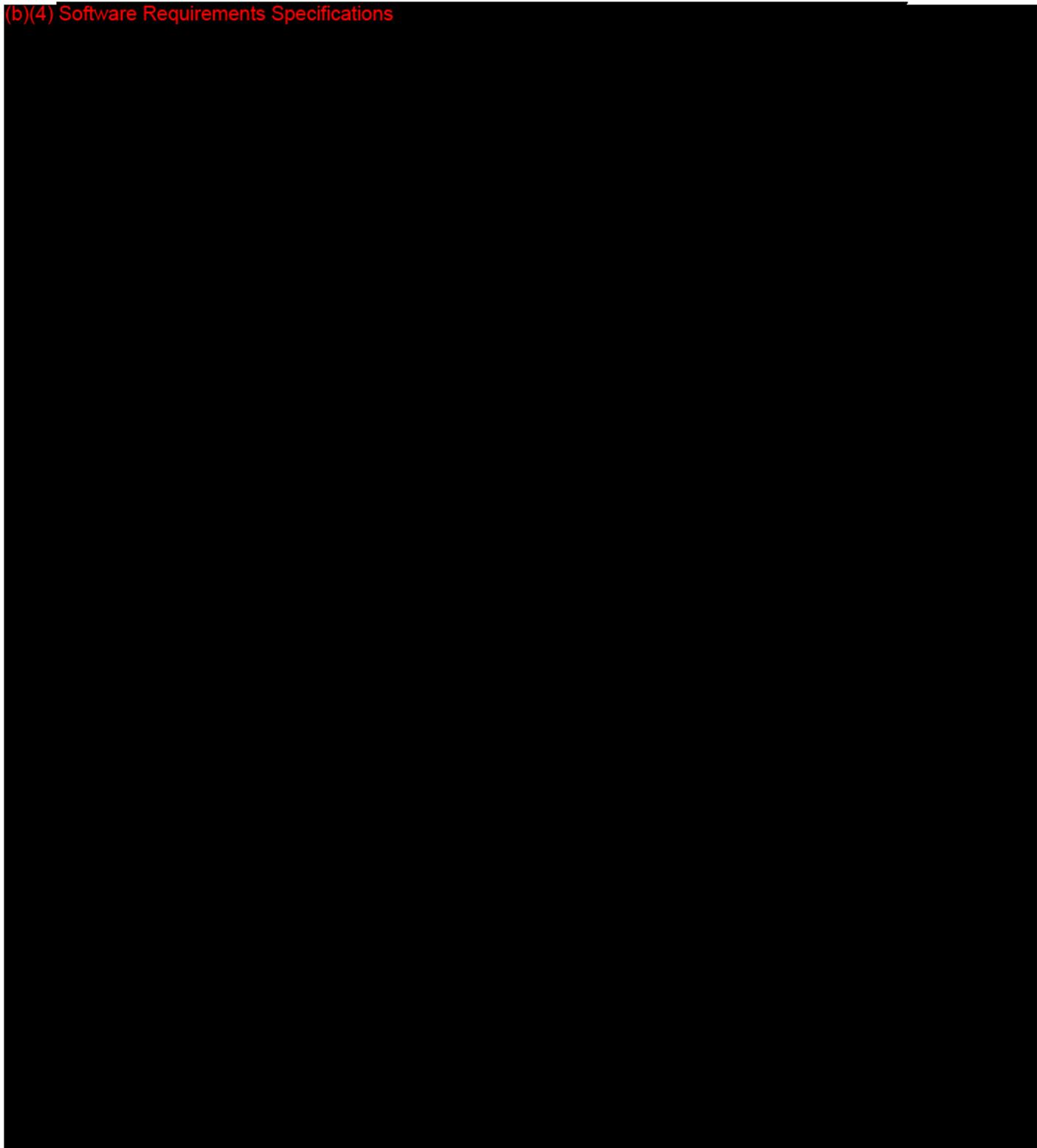




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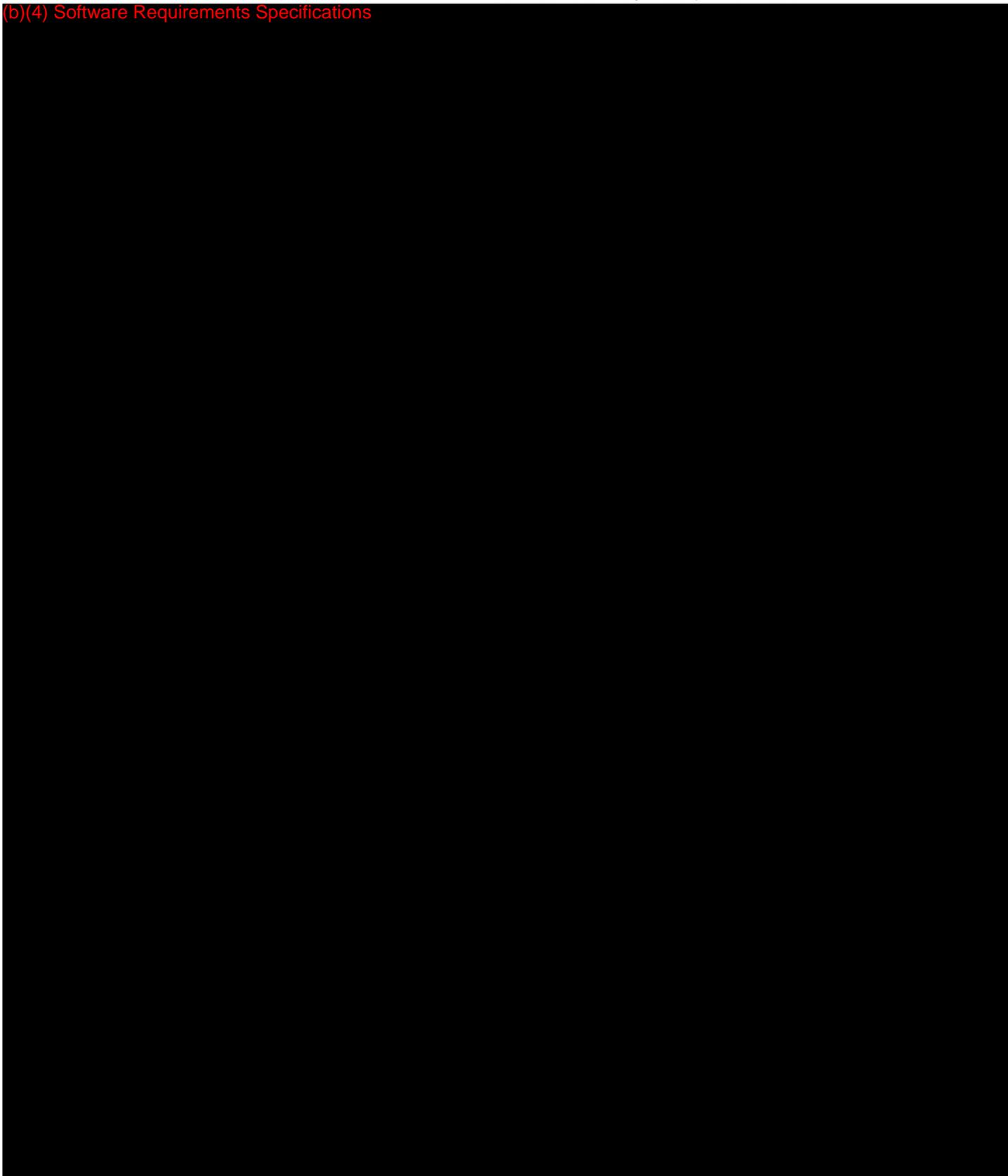


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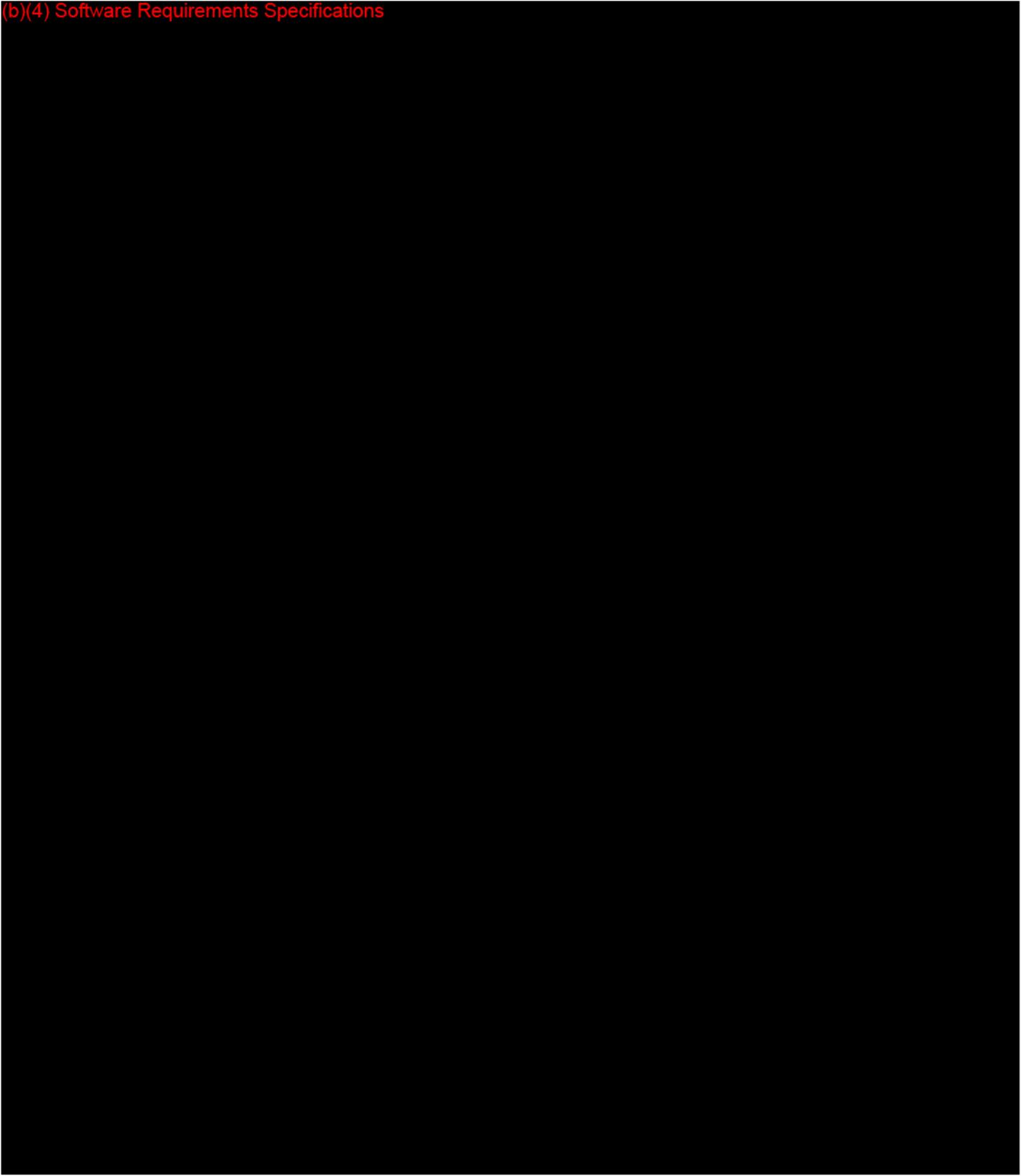
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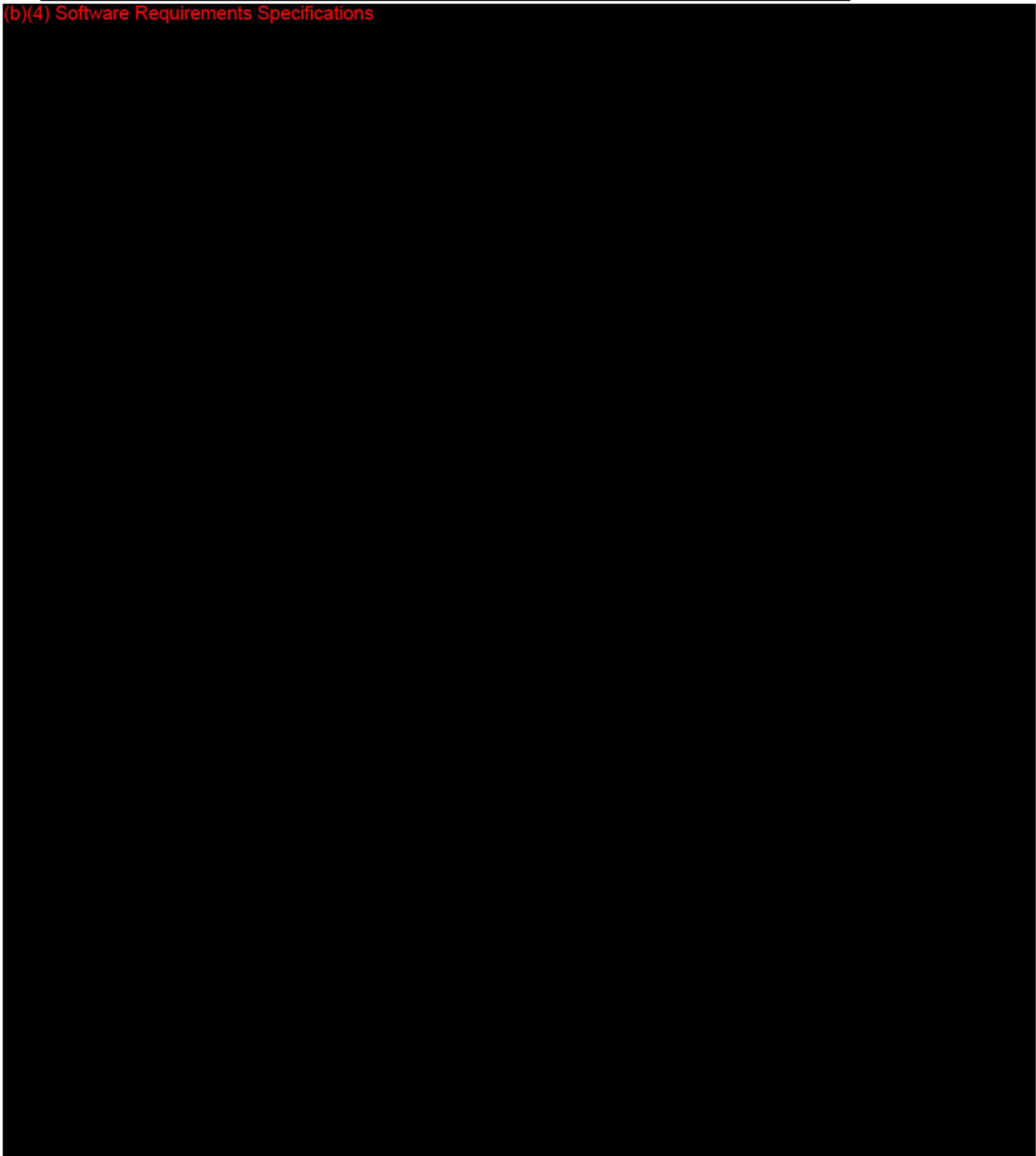
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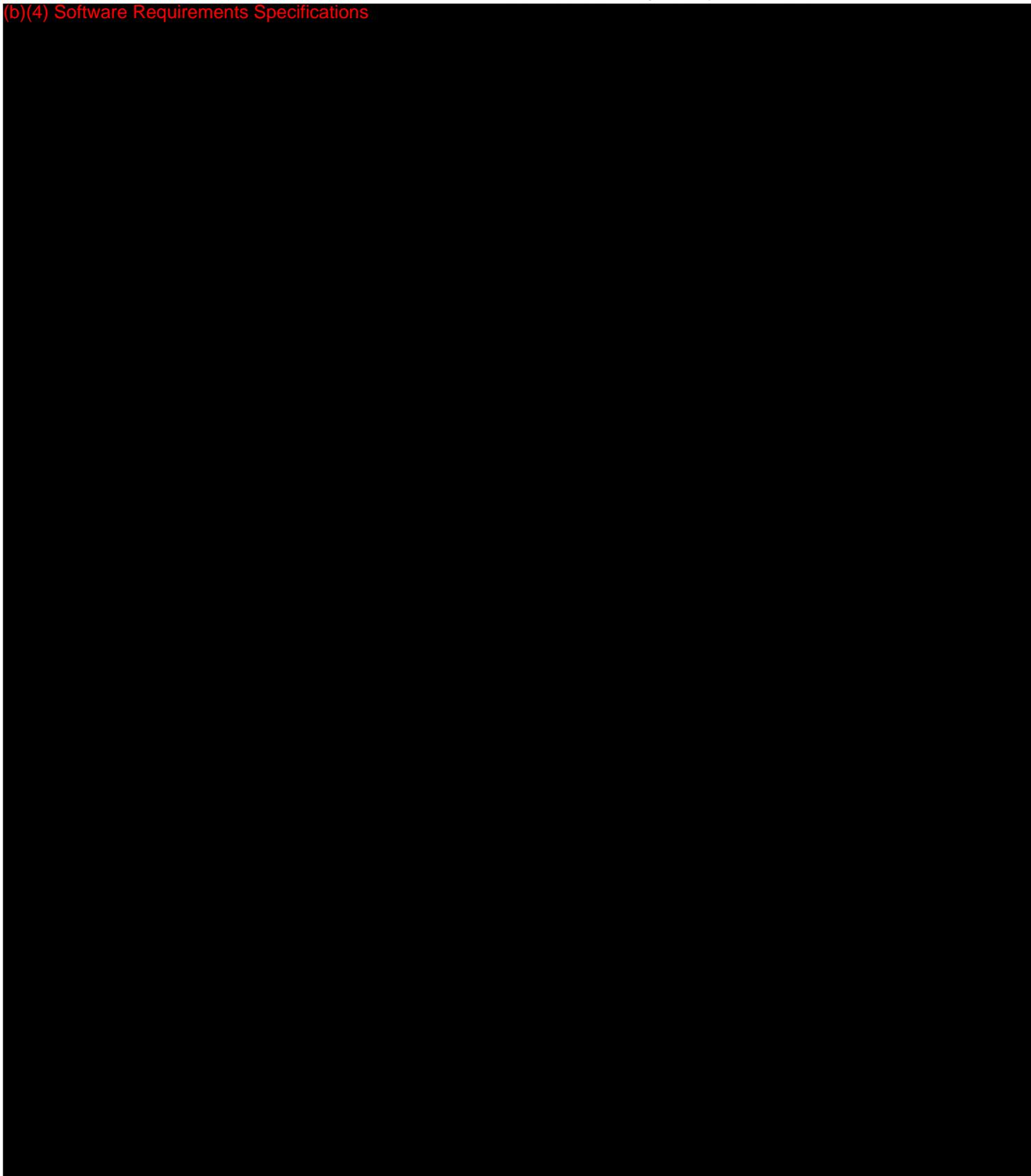
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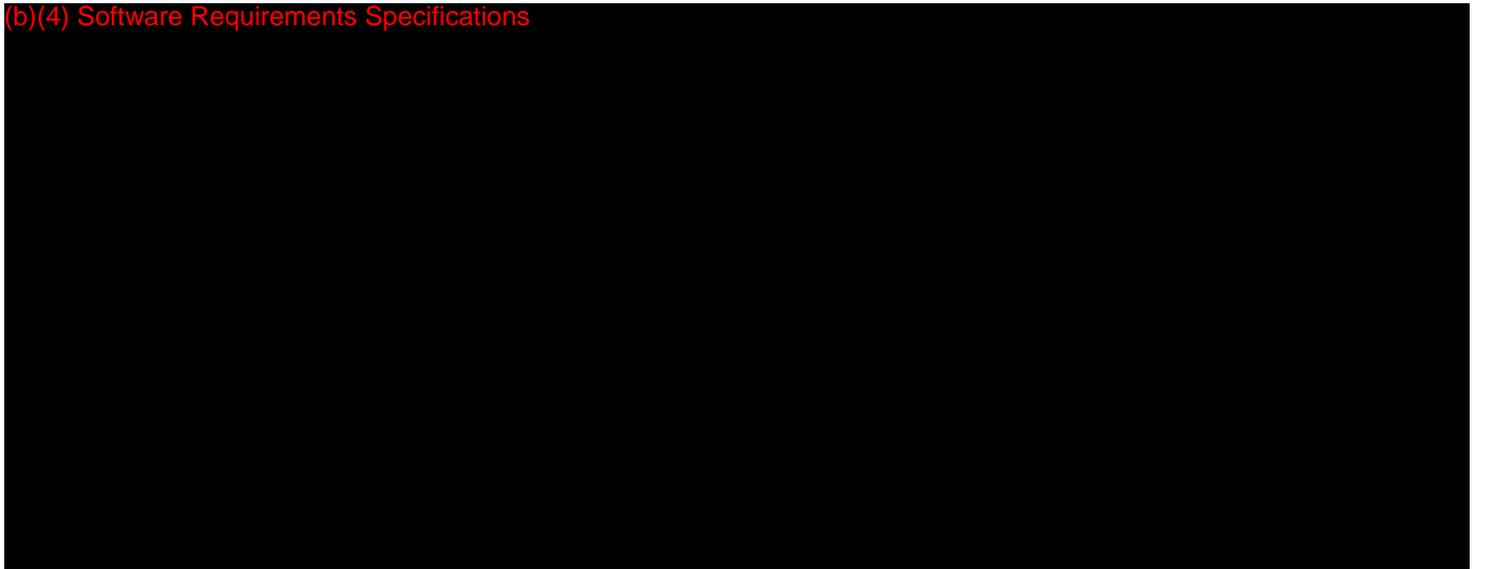


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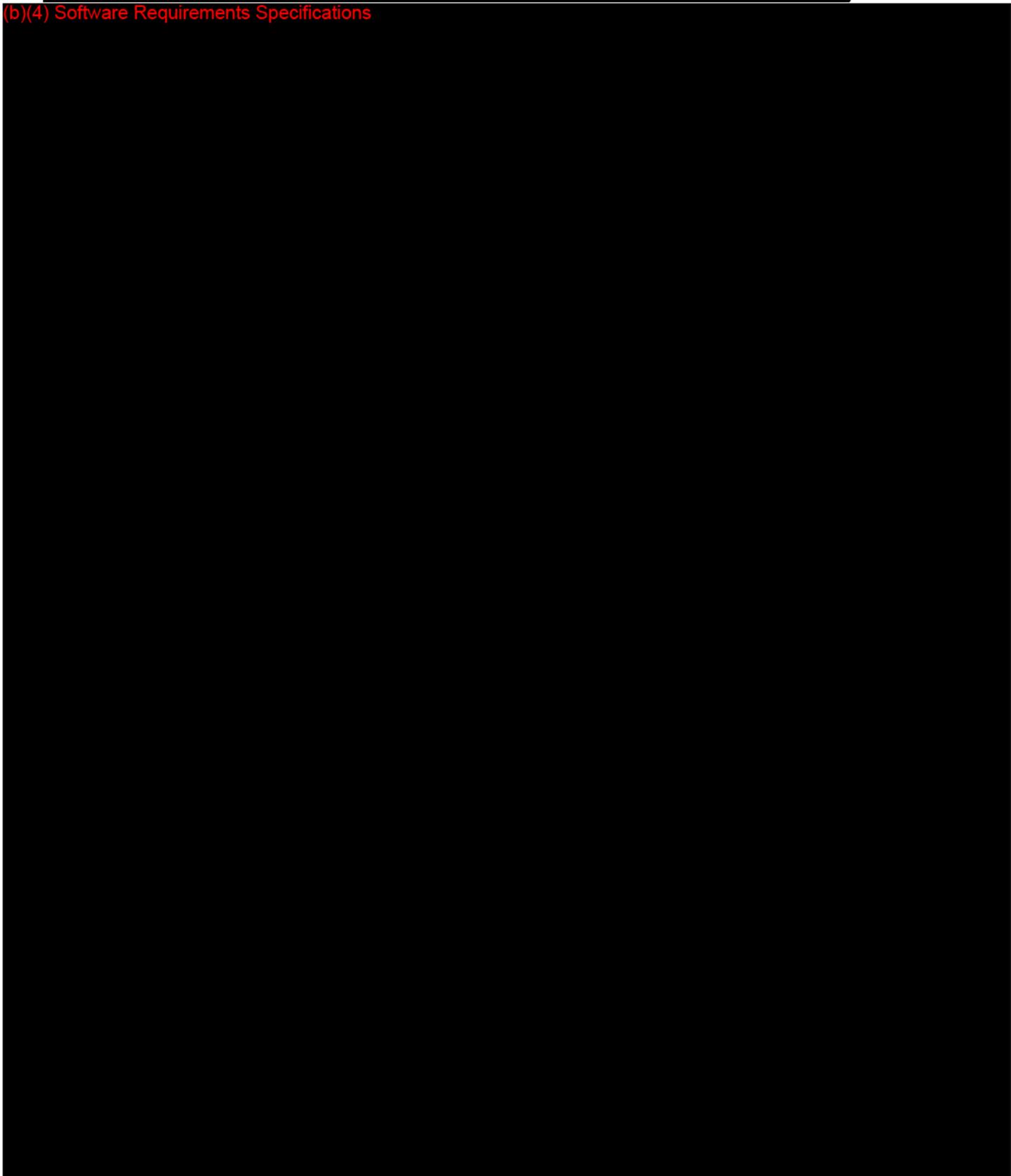
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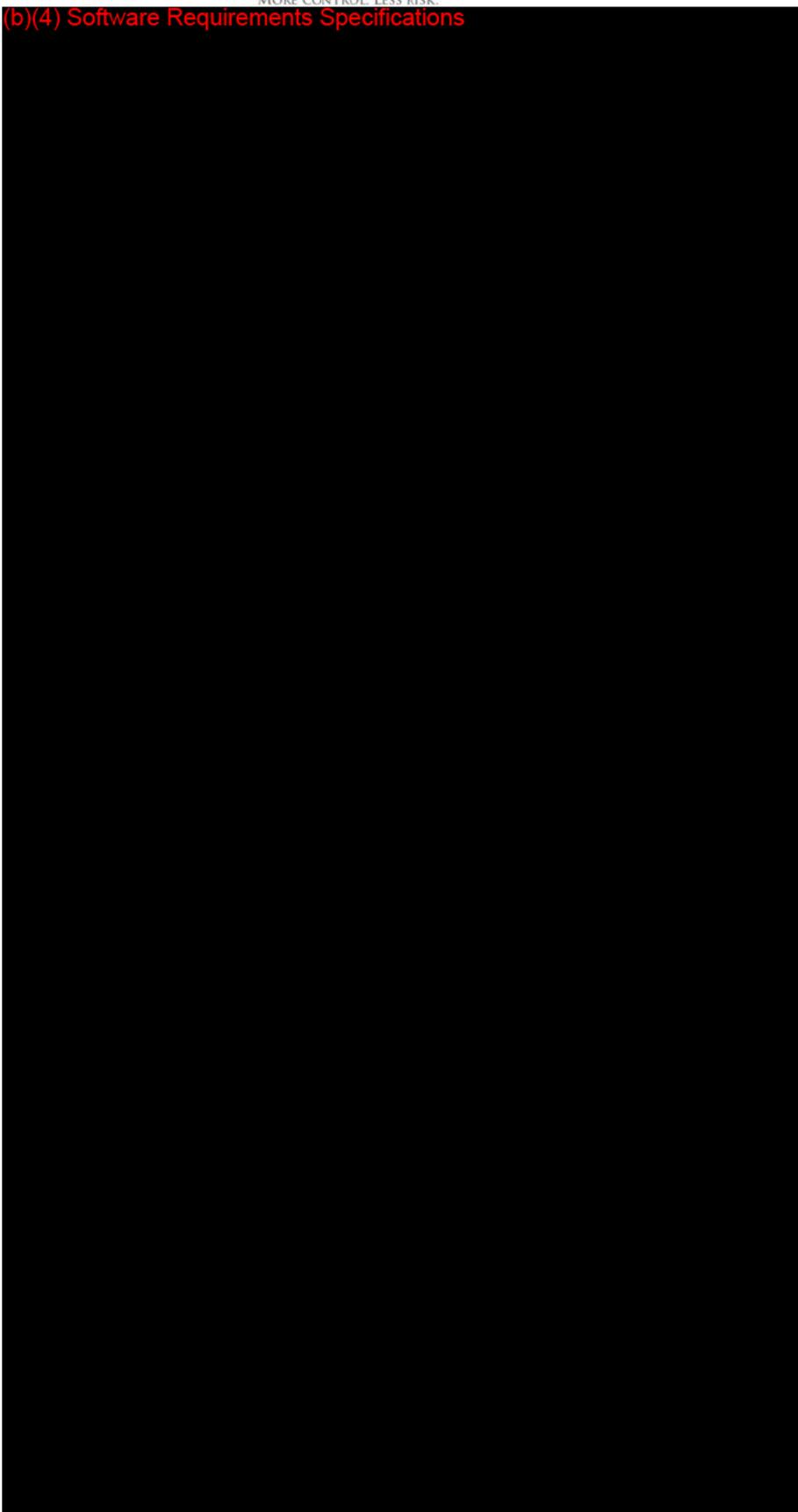




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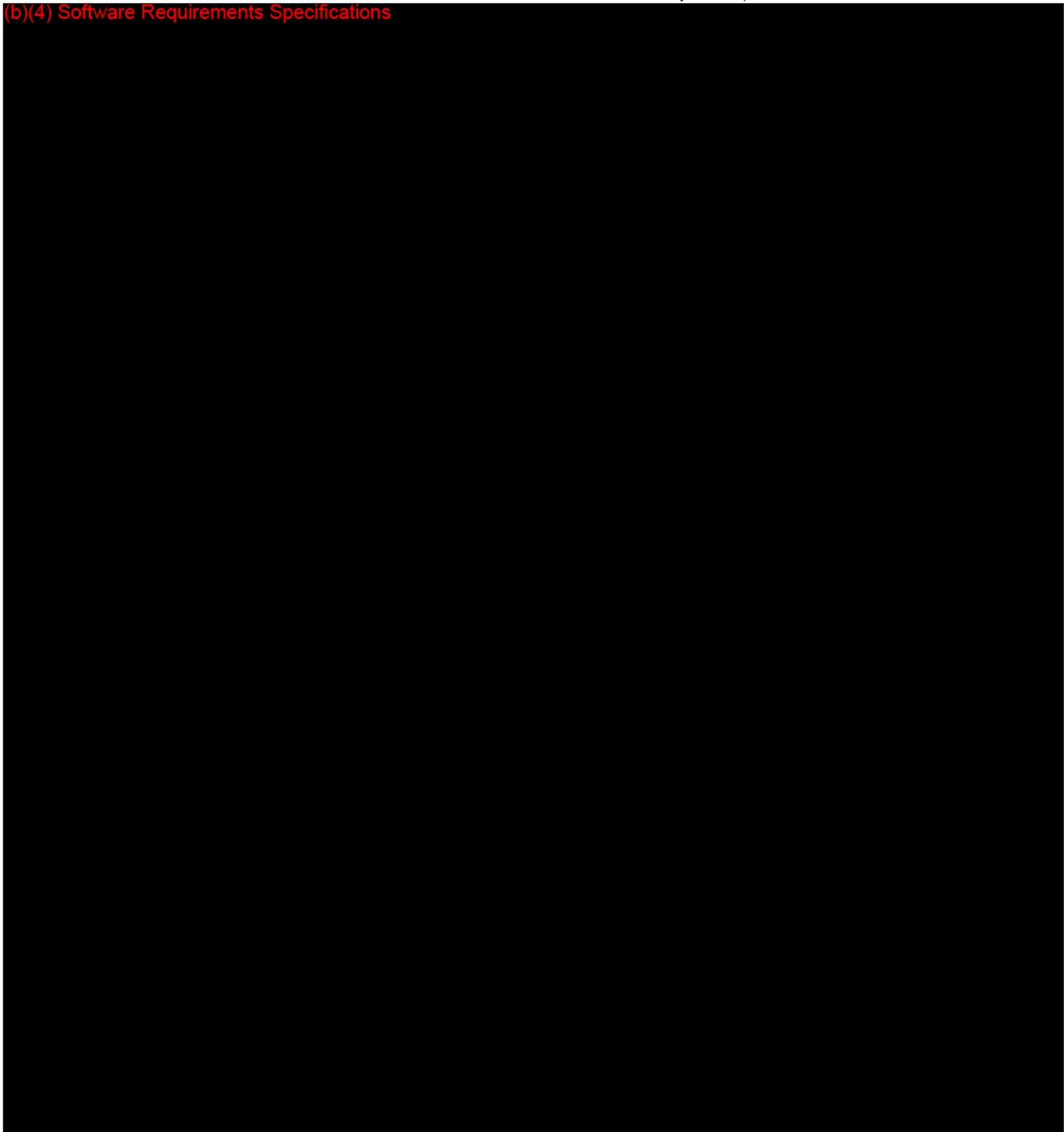
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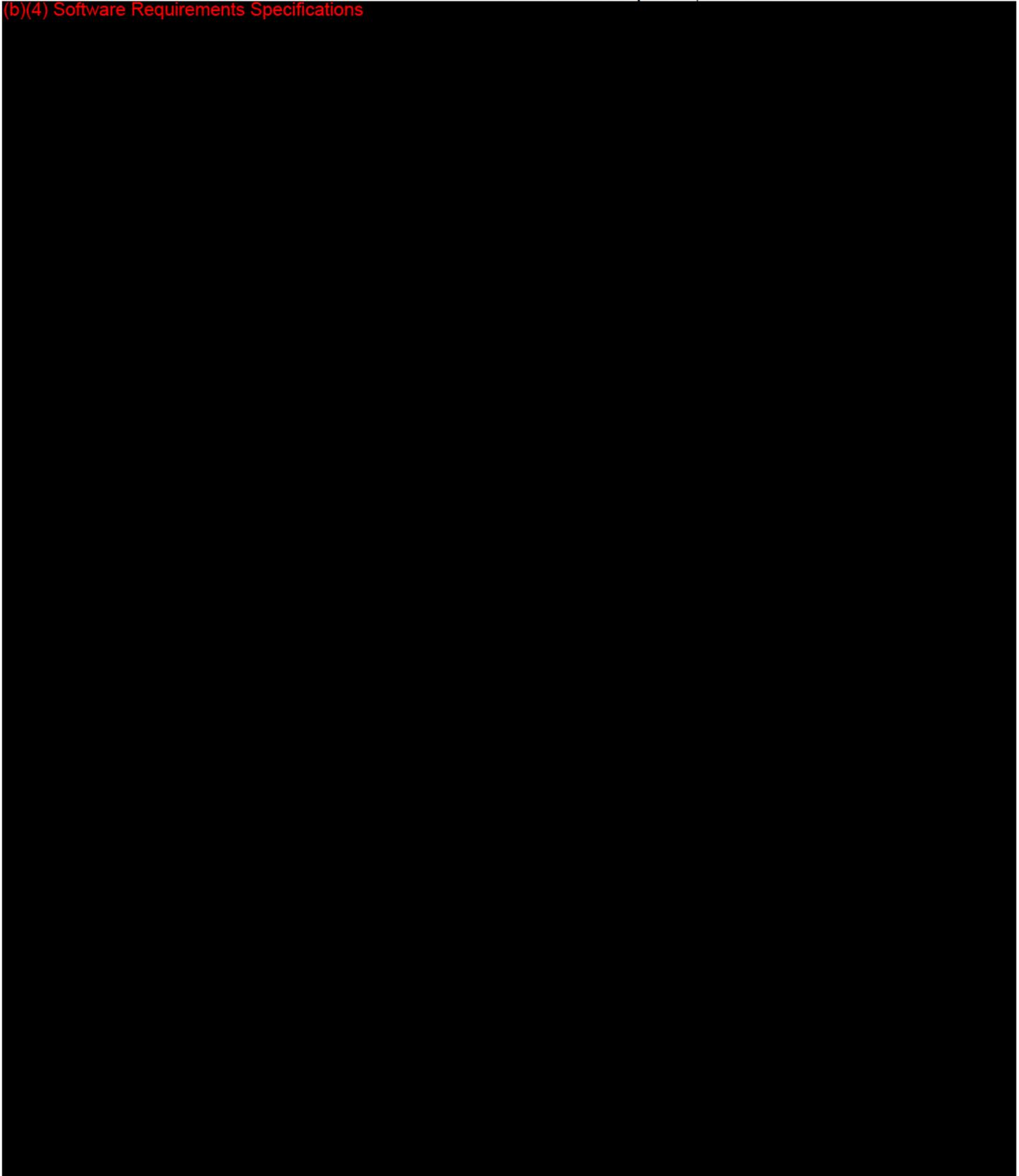




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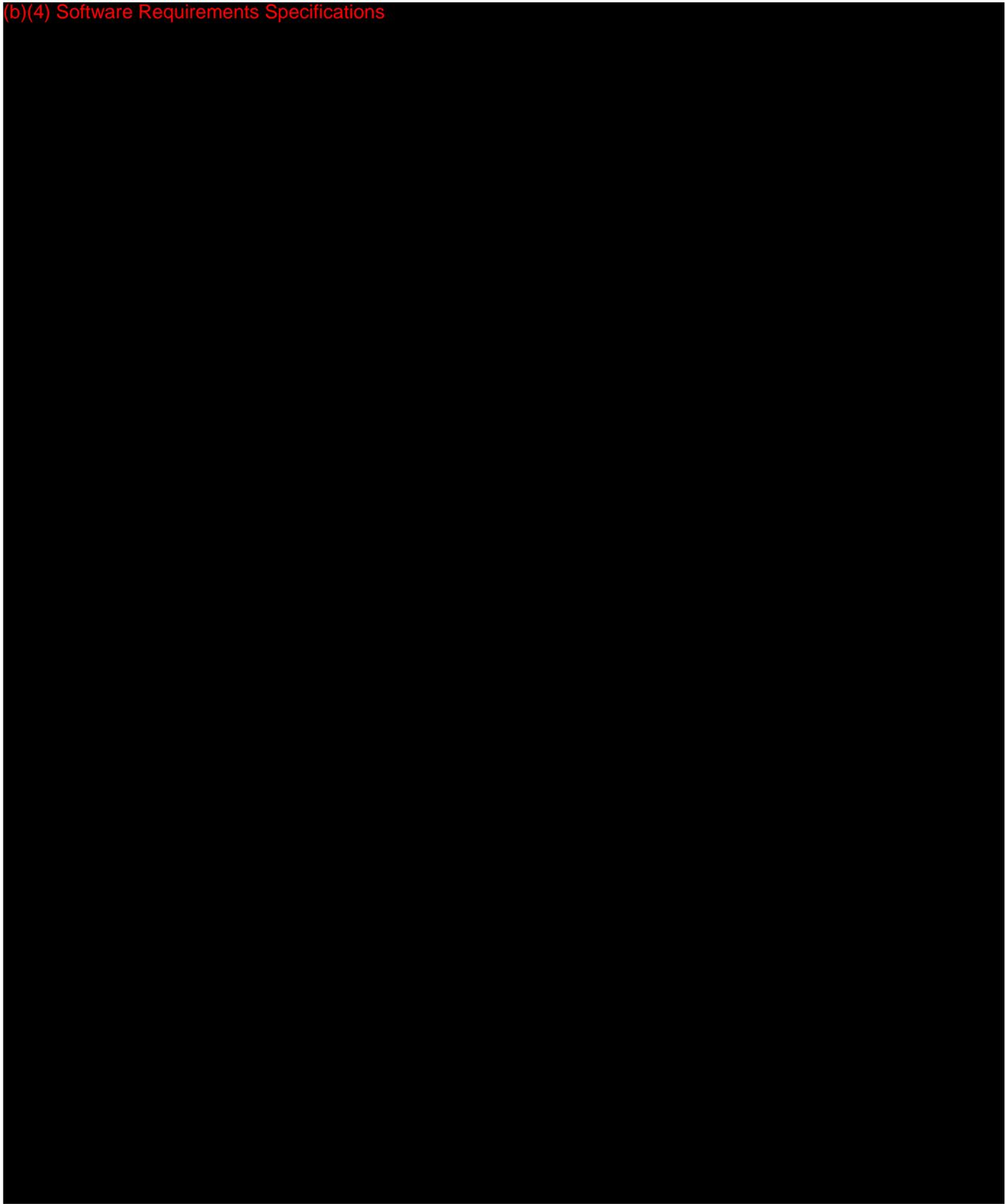


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ATTACHMENT 8-2

Software (b)(4) Software Information

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		(b)(4)	05.01.2012	(b)

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(b)(4)	(b)(4) Software	Quality Assurance

PROGRAM NAME: gCRM
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(b)(4) Software Information	ECTN	Title	Name	Signature	Date	 ST. JUDE MEDICAL <small>MORE CONTROL. LESS RISK.</small>	St. Jude Medical MediGuide Navigation Systems Advanced Technology Center P.O.B 15003, Haifa 31053, Israel
		SW proj leader	(b)(6)		9/1/12		
		SW Dir				7/2/12	TITLE
		Proj Dir				3-1-12	(b)(4) Software Information
		SW Project leader				1/1/12	
	QA Dir				2 Jan 2012	SIZE	DOC. NO.
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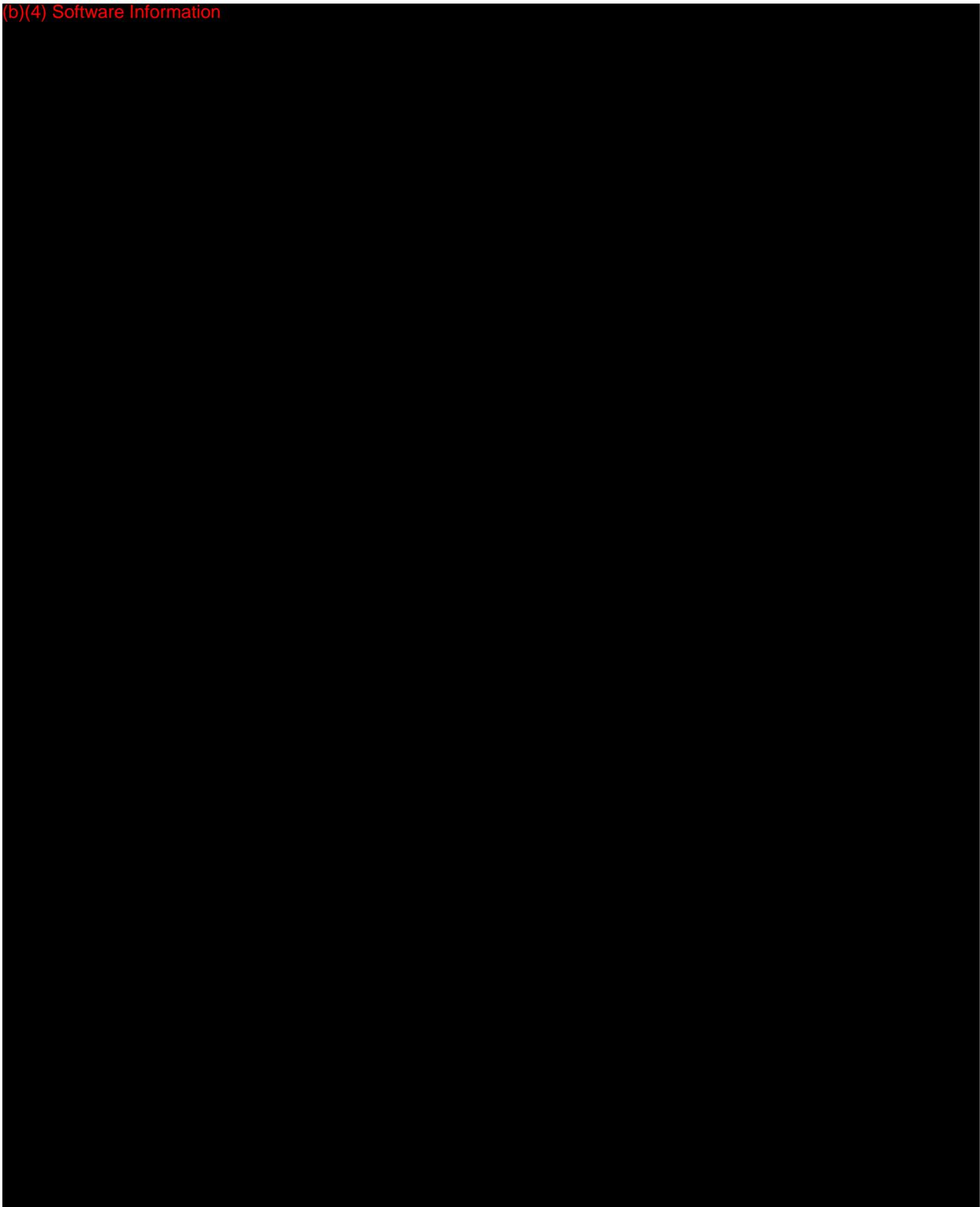


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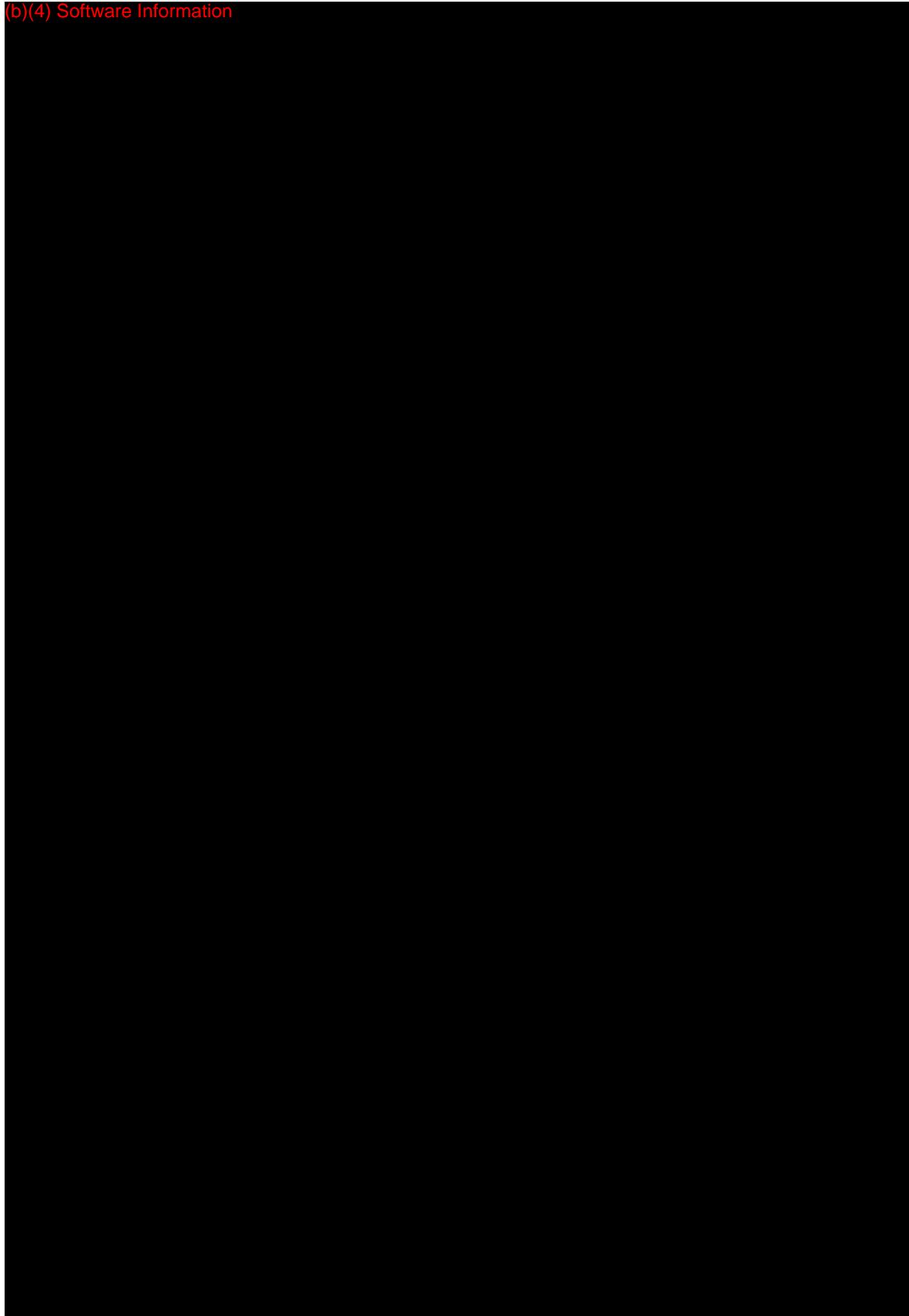


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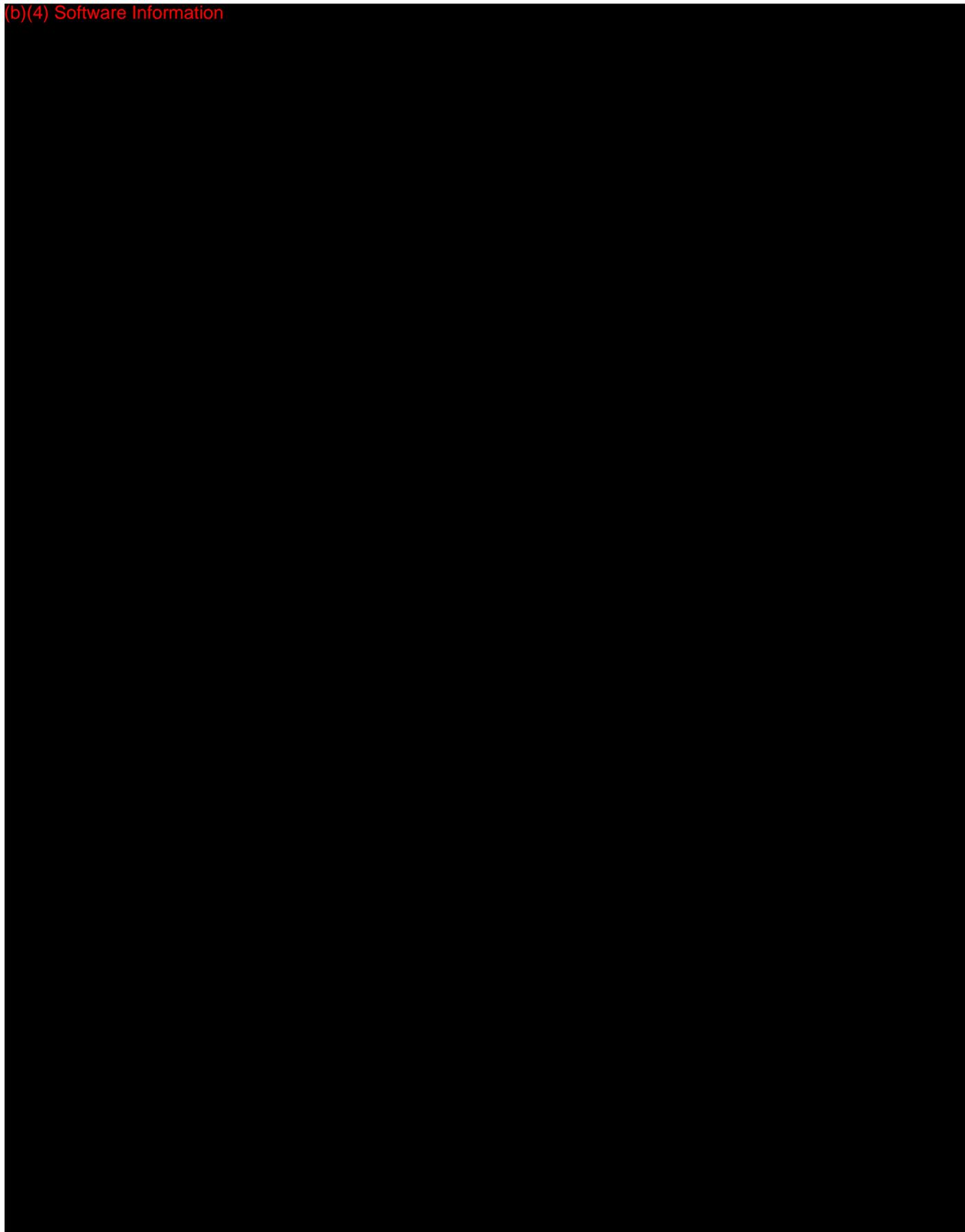
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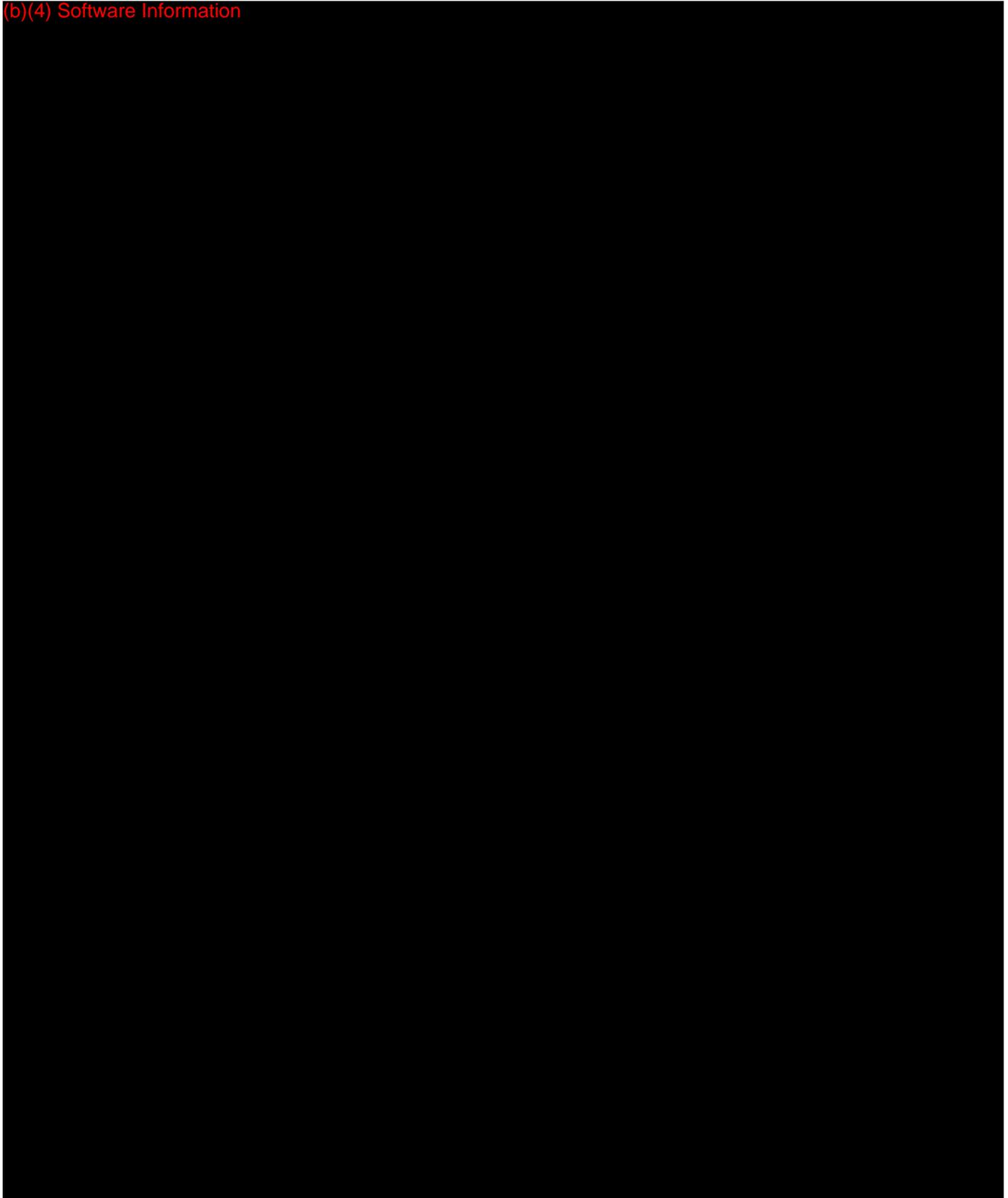


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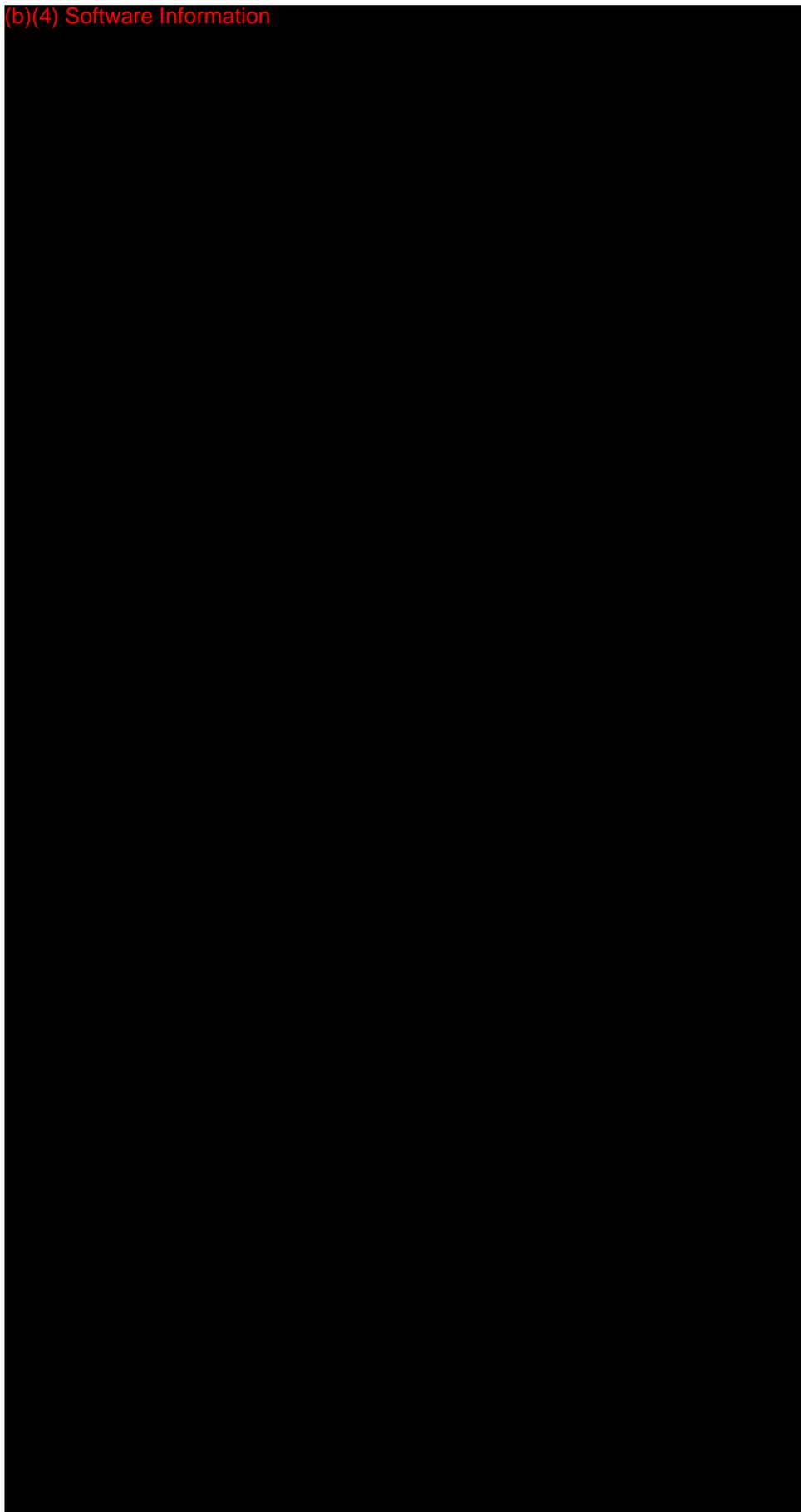


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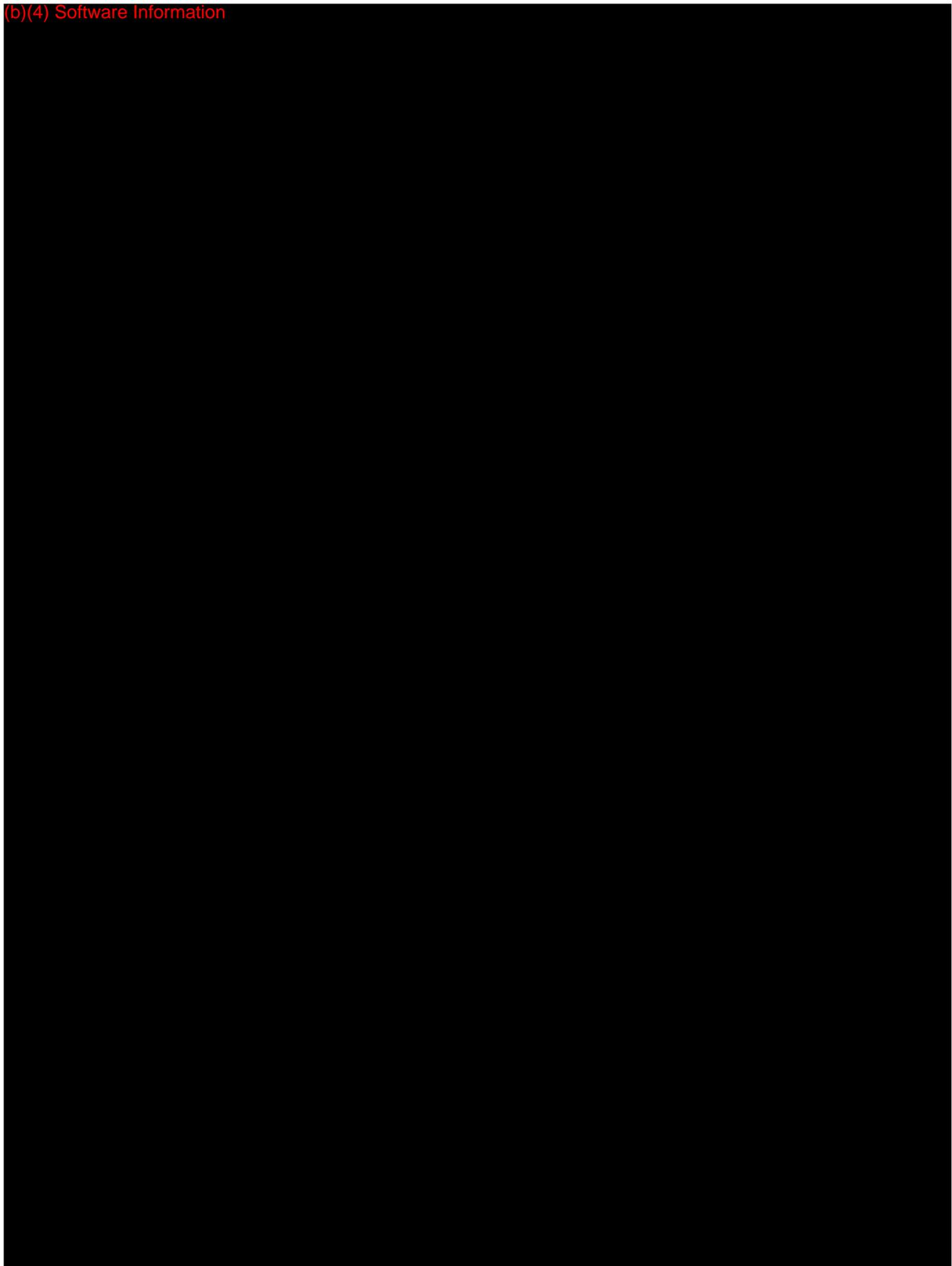


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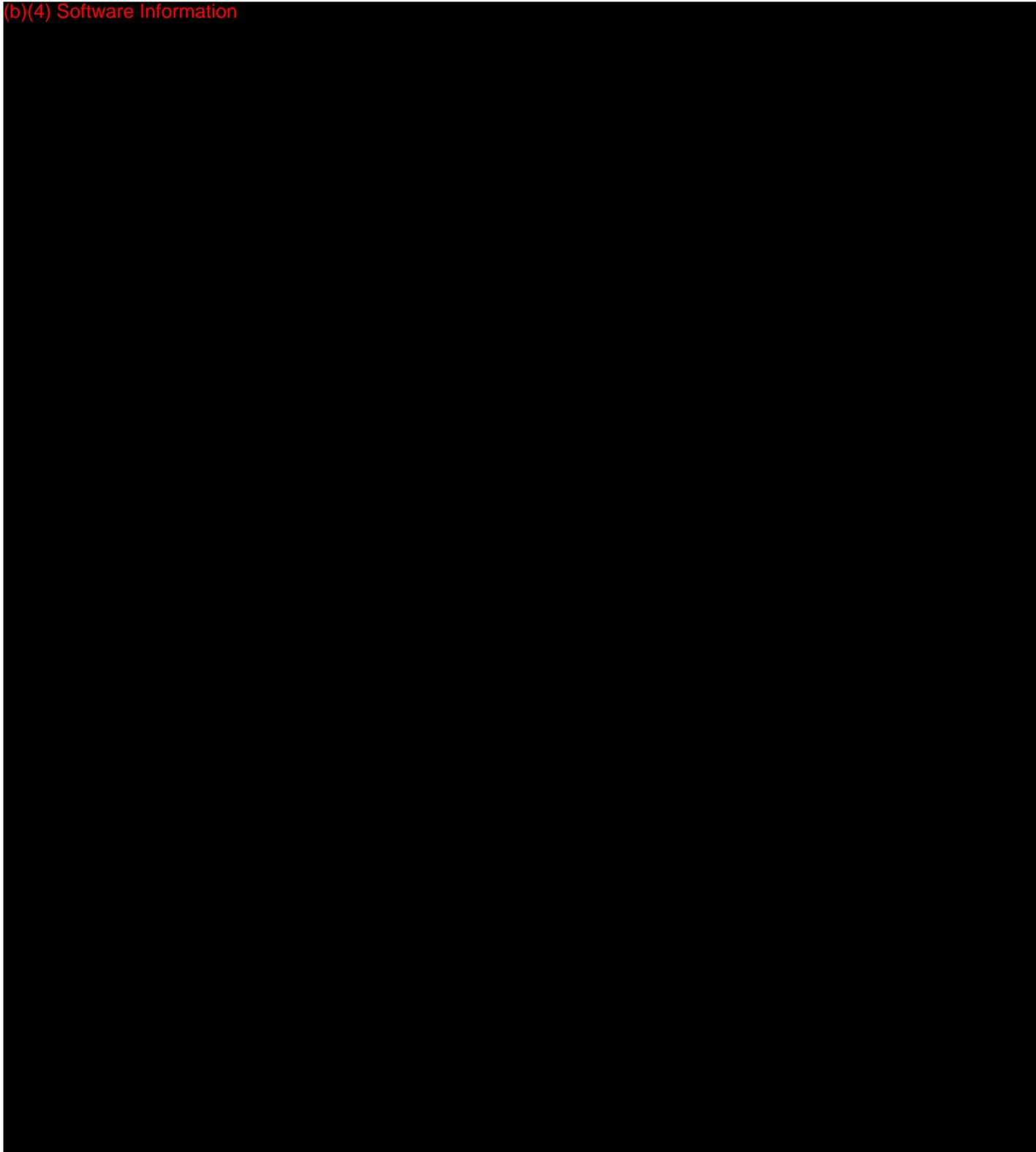


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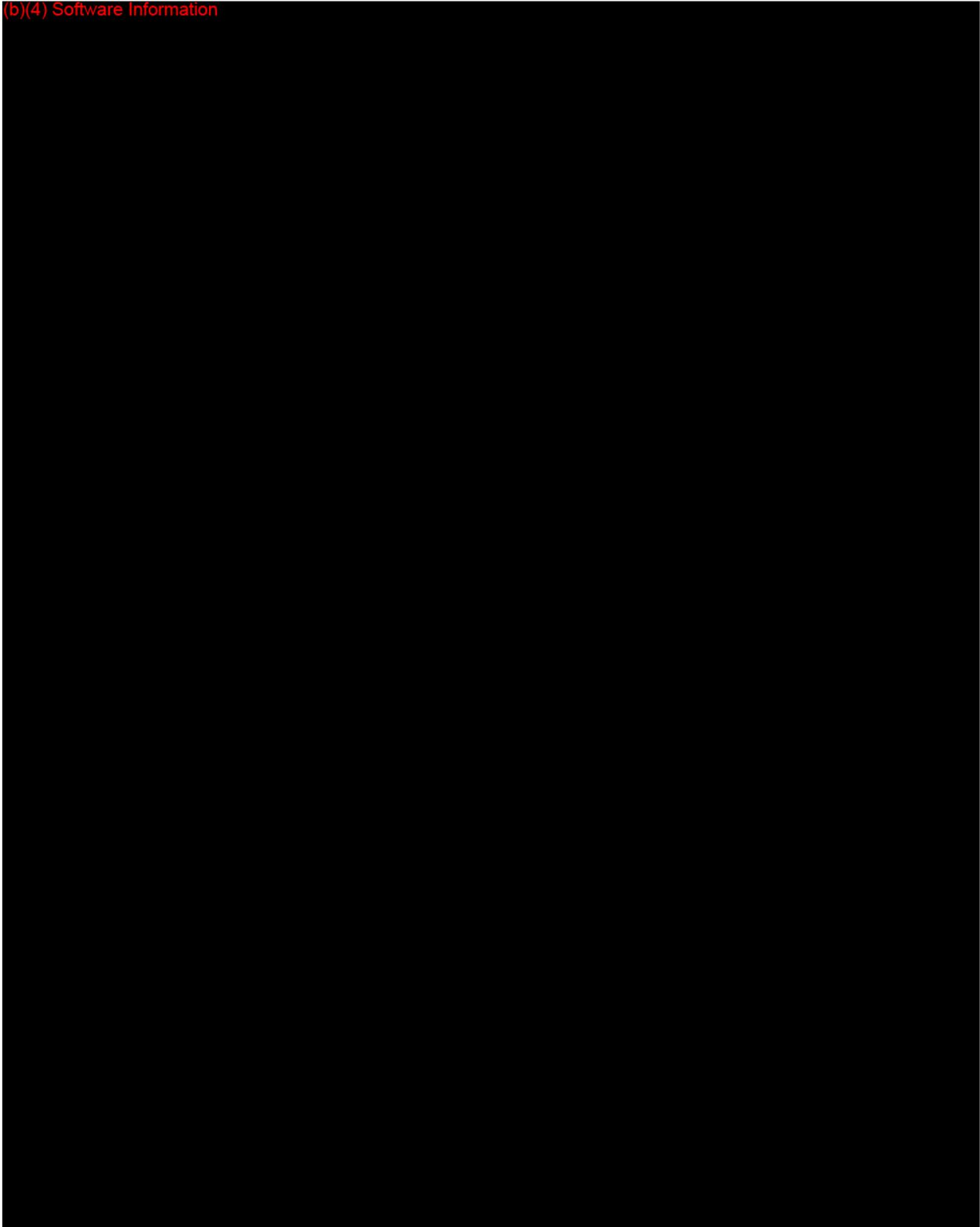


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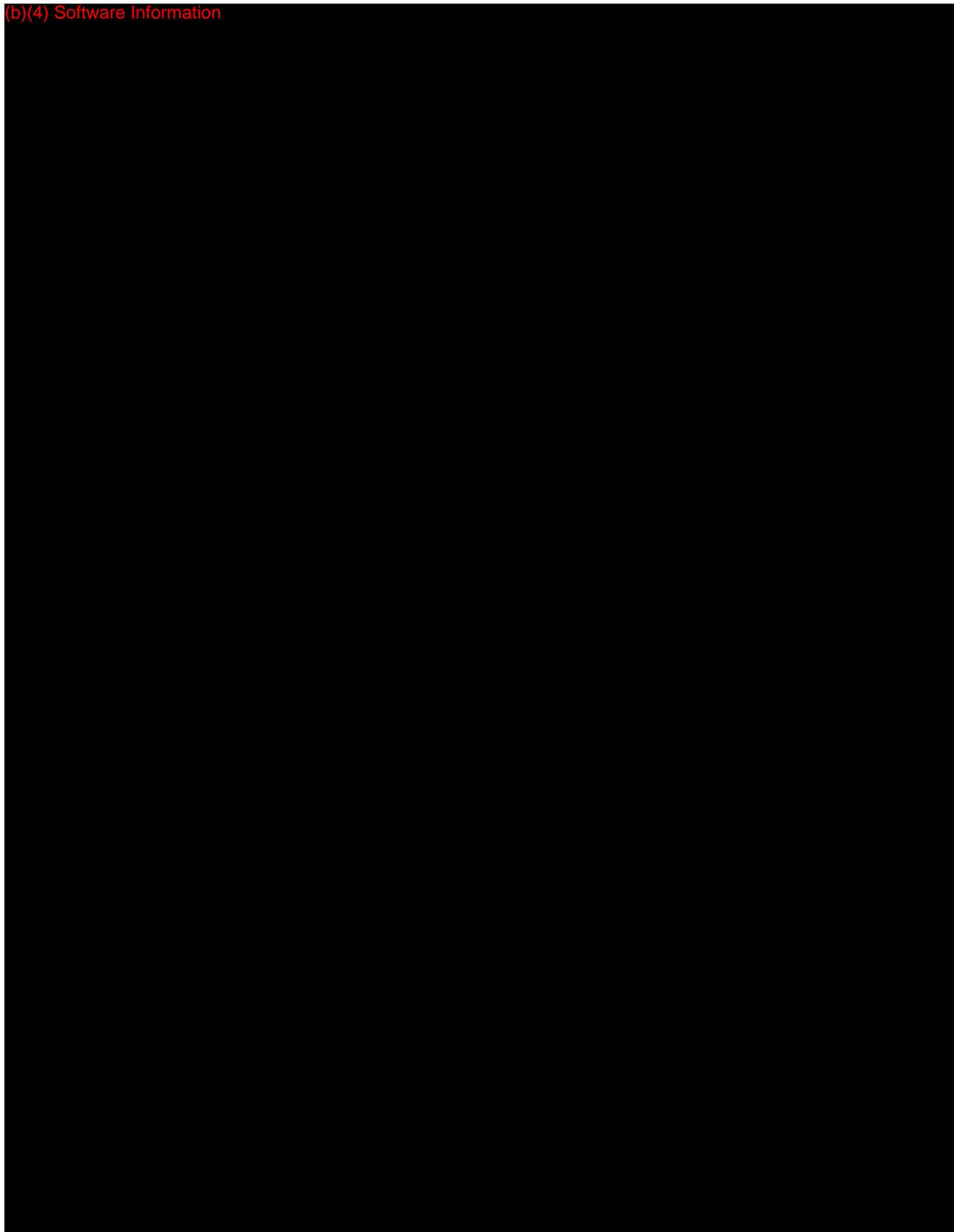


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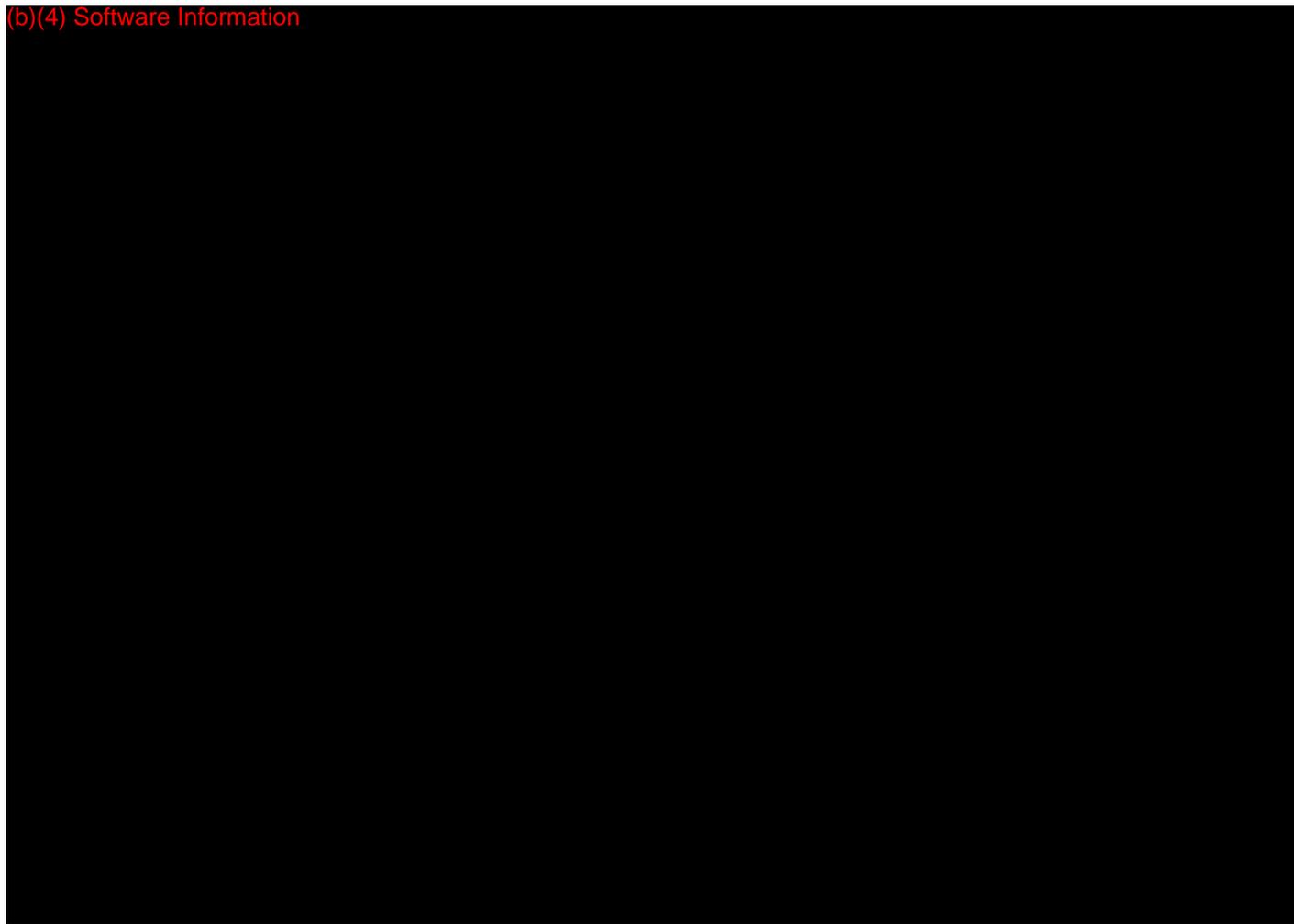


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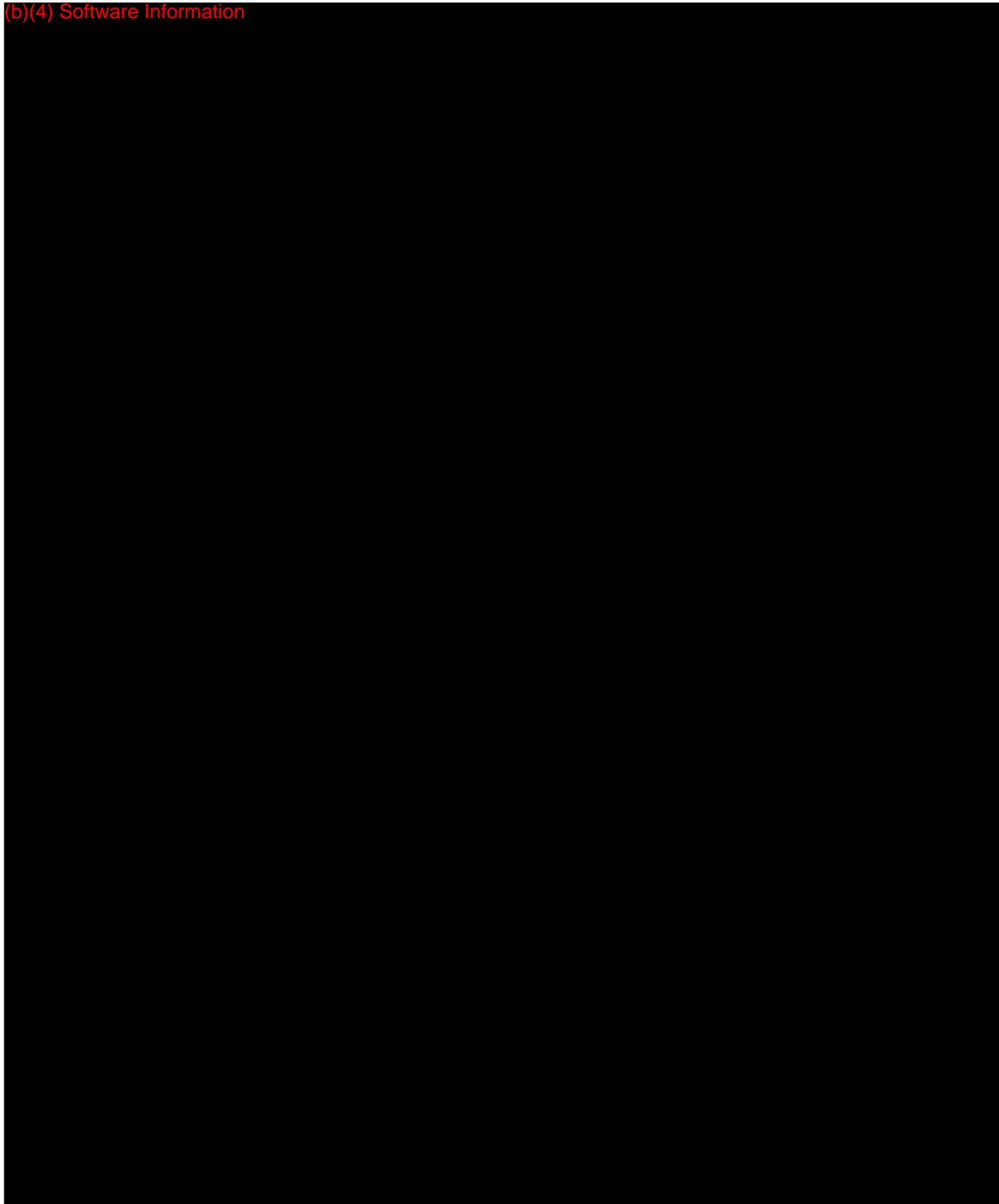


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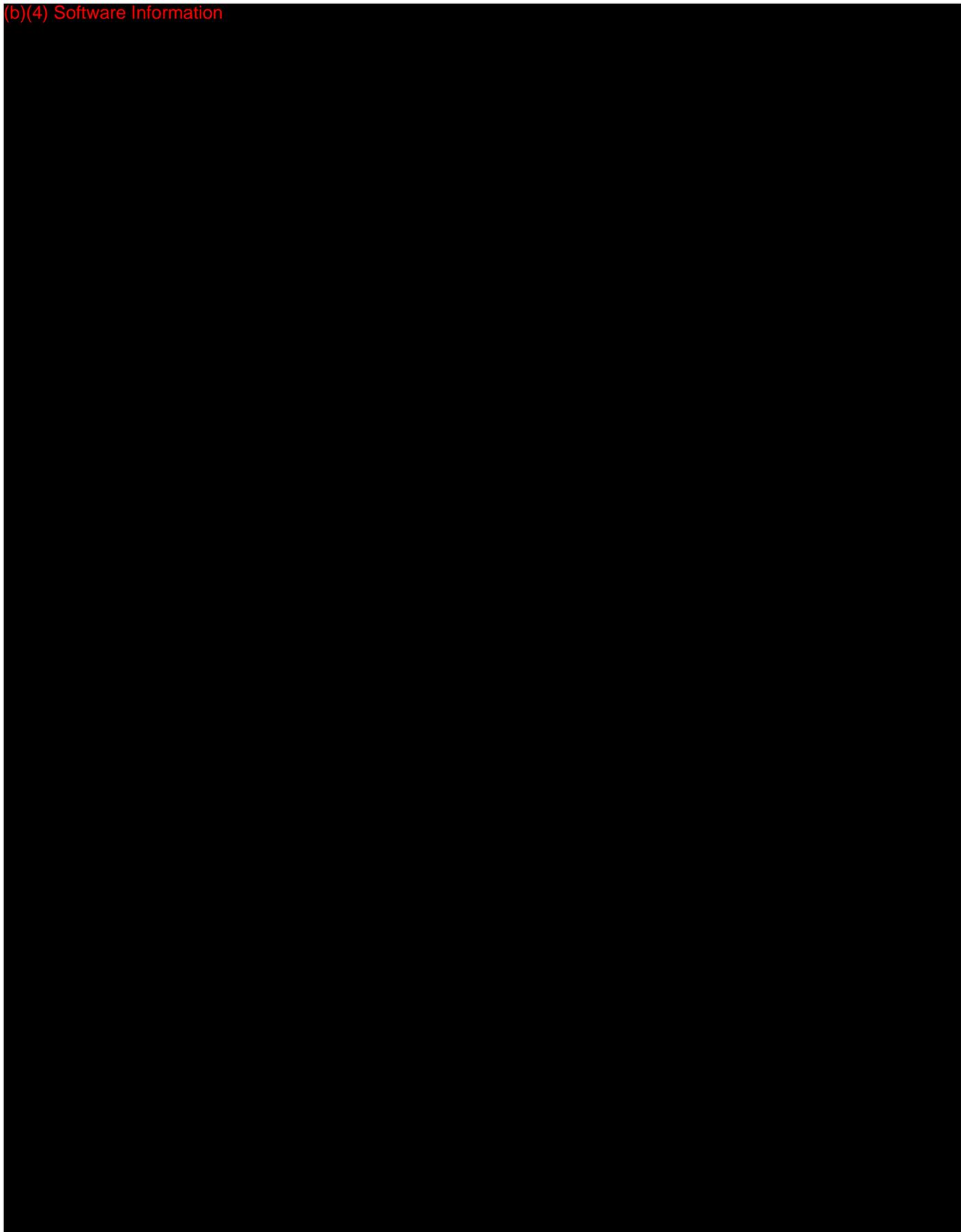


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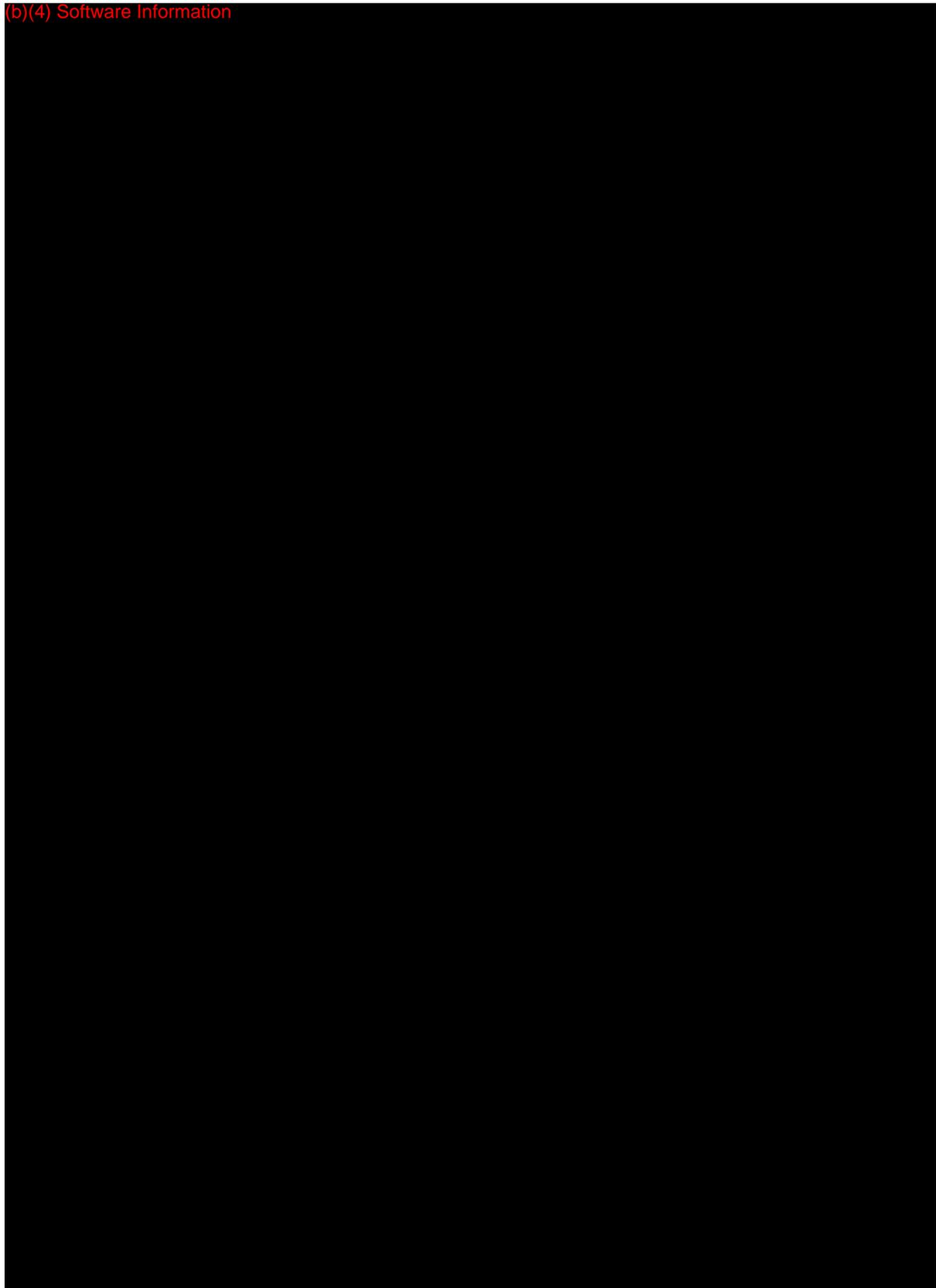


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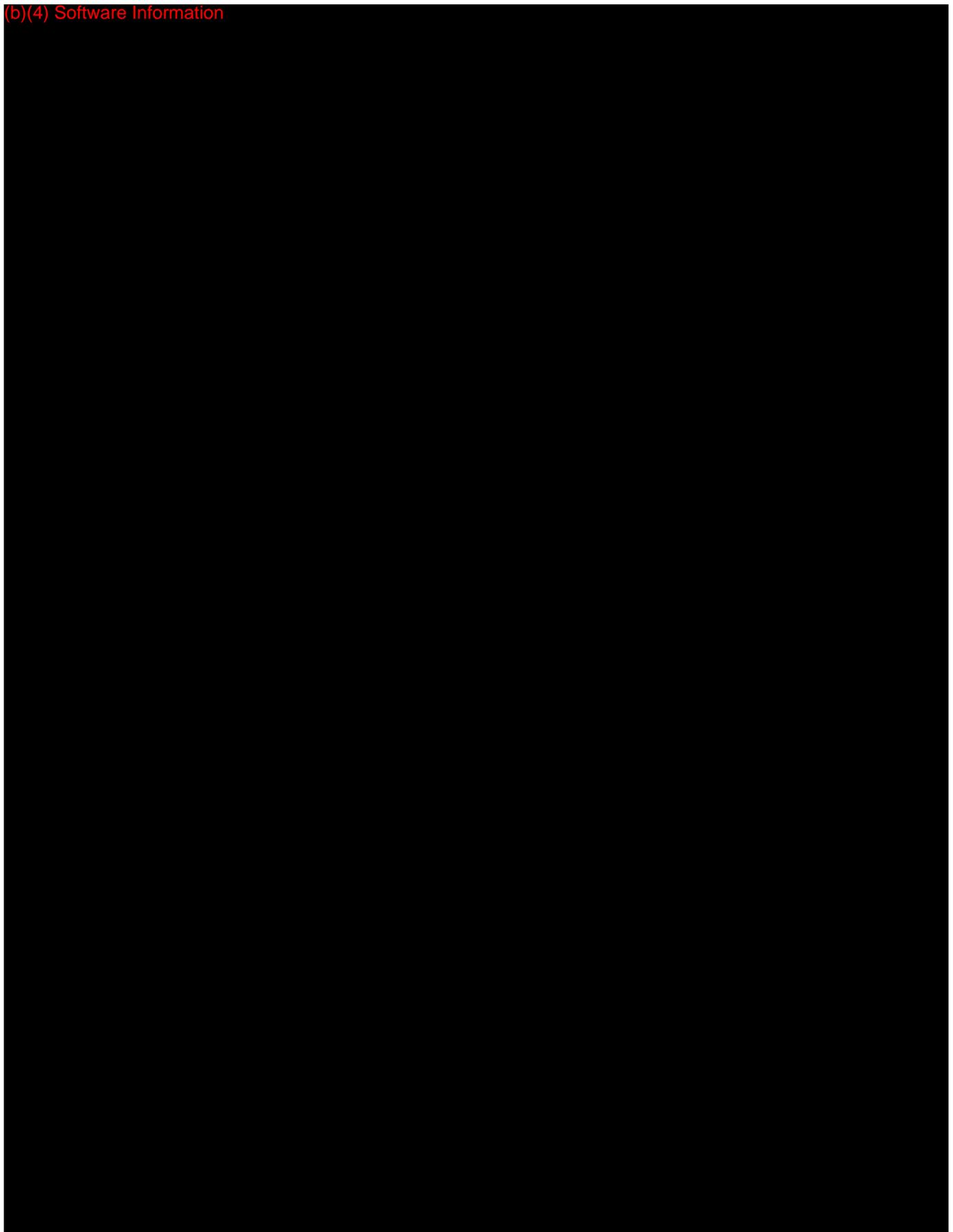


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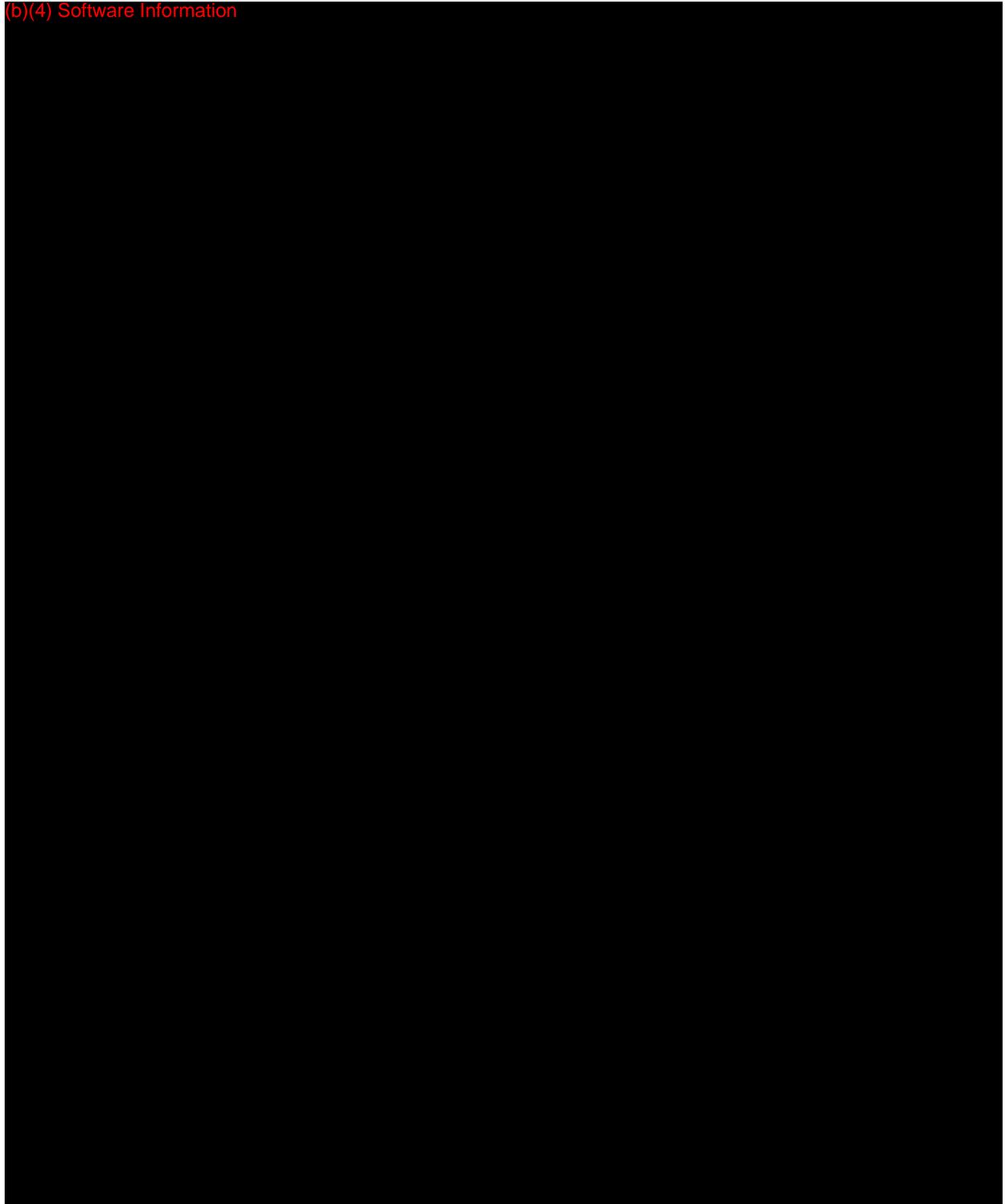


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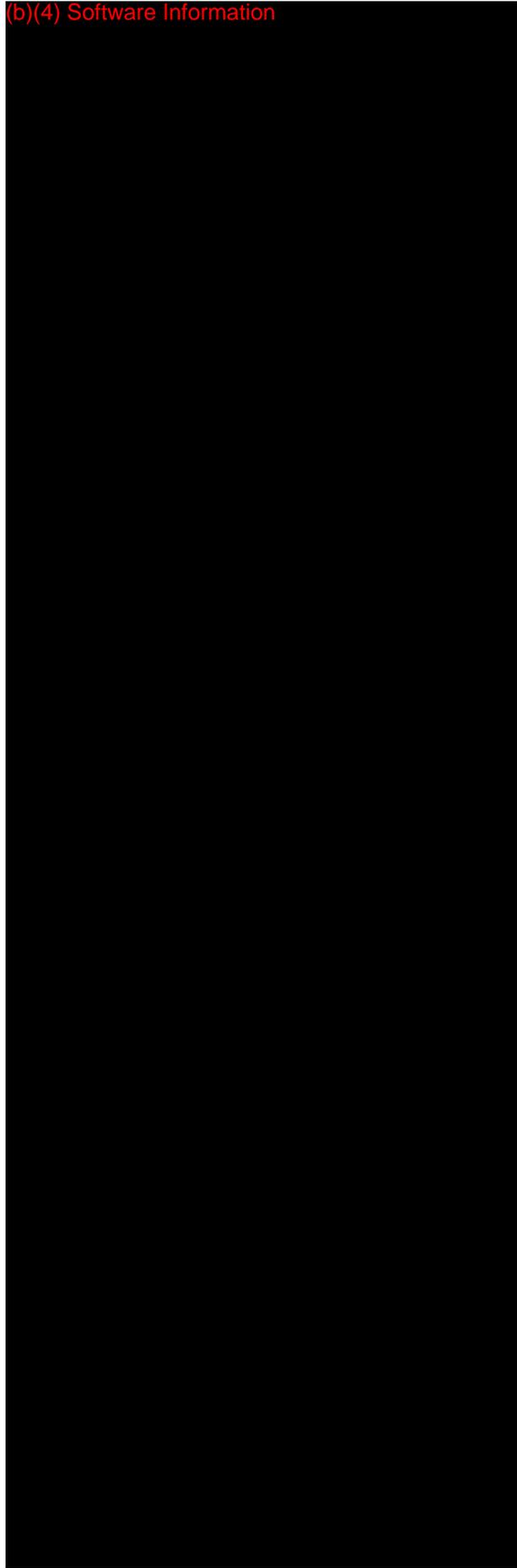


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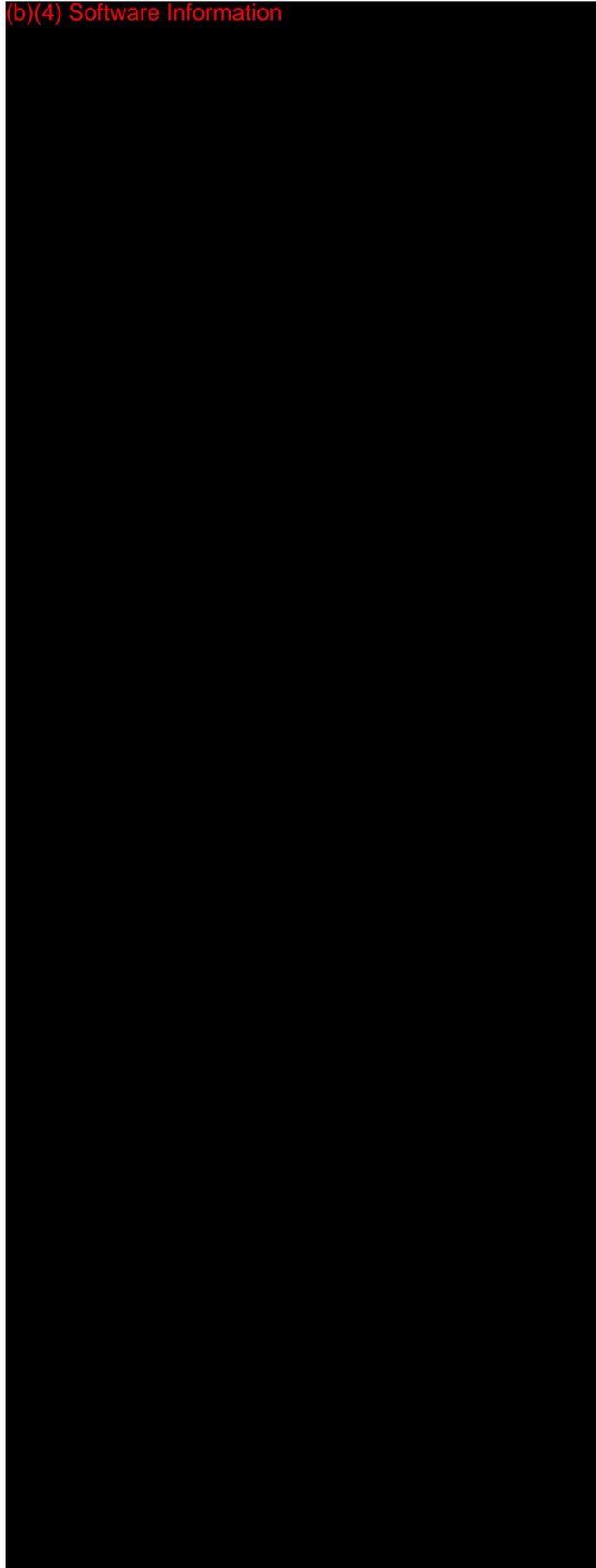


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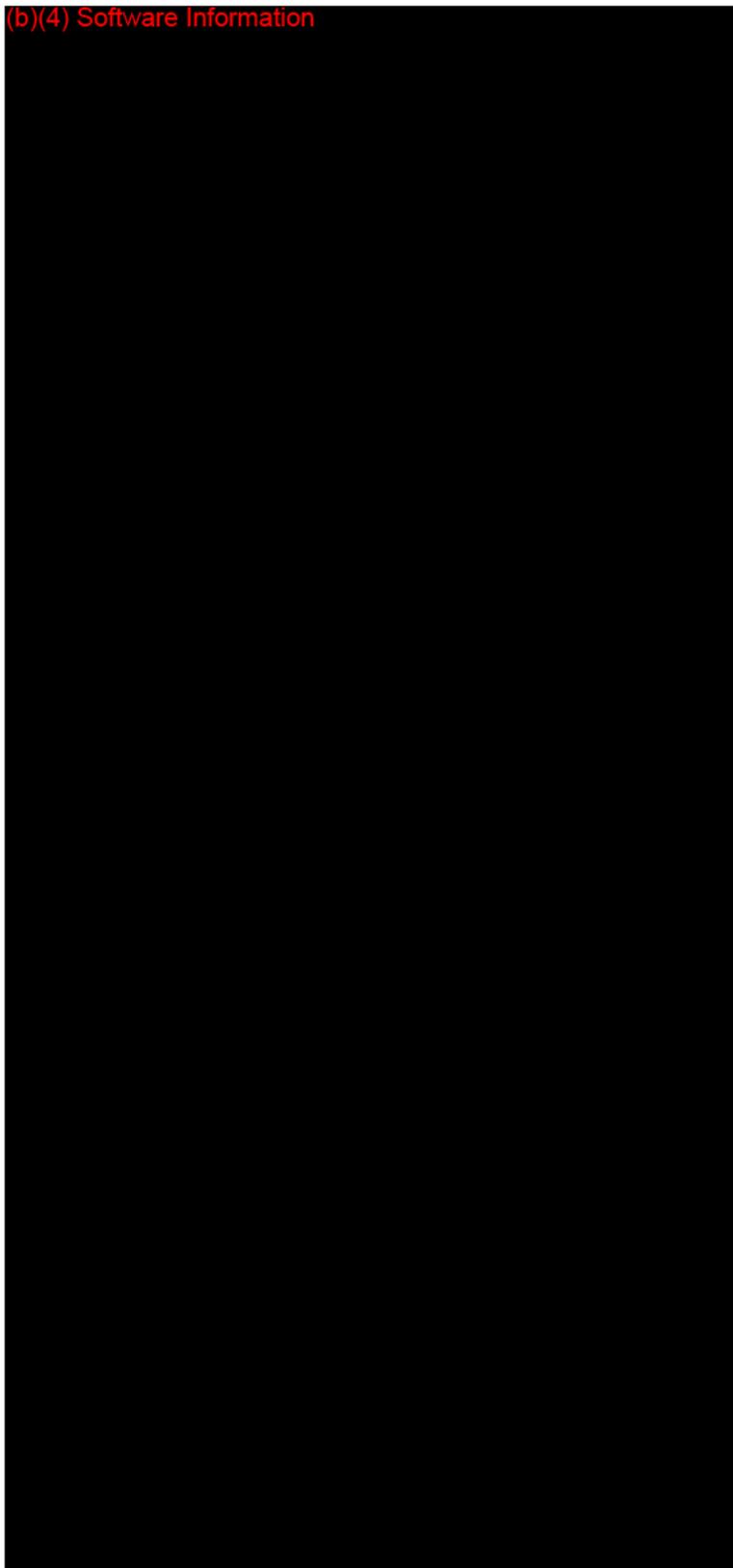


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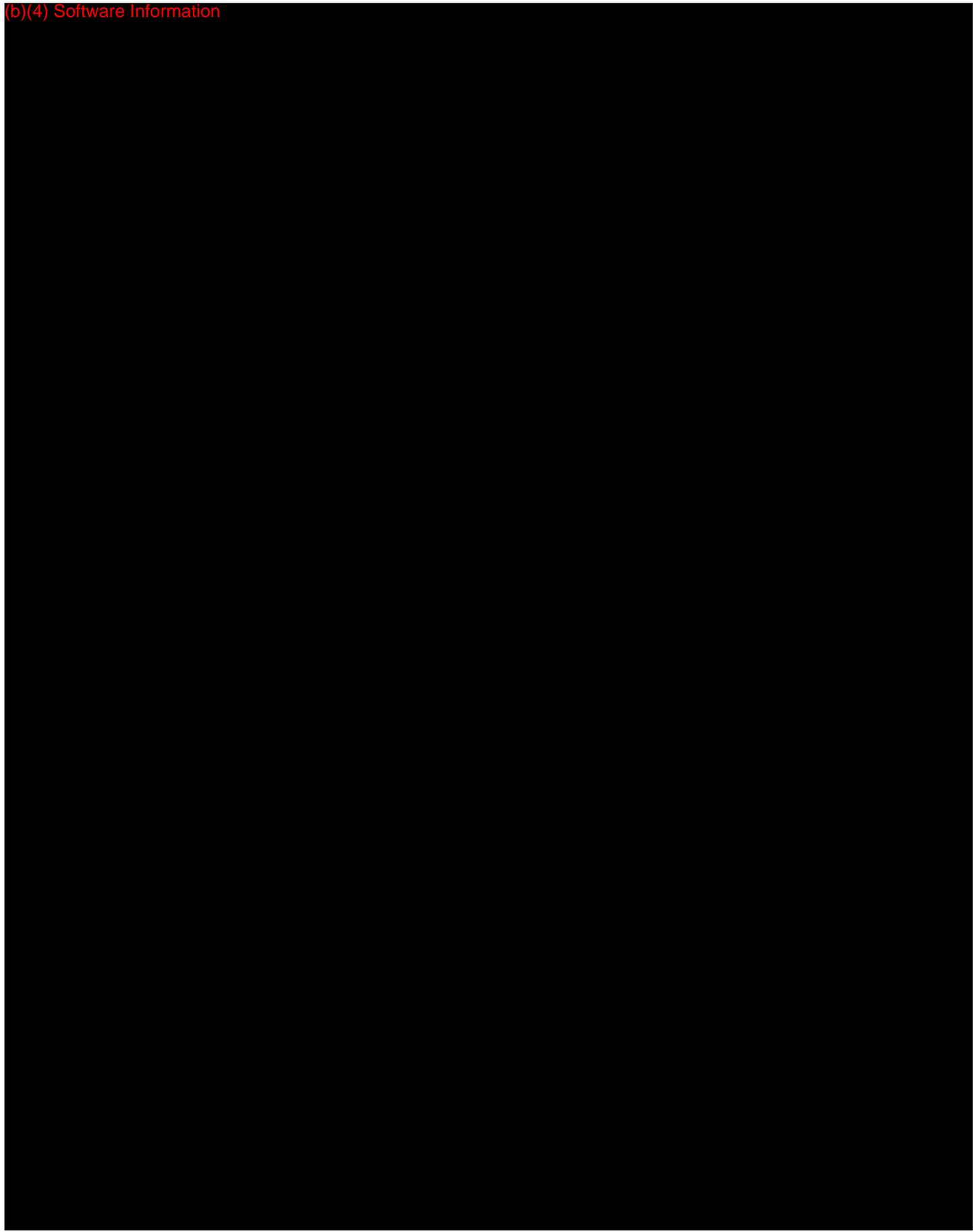


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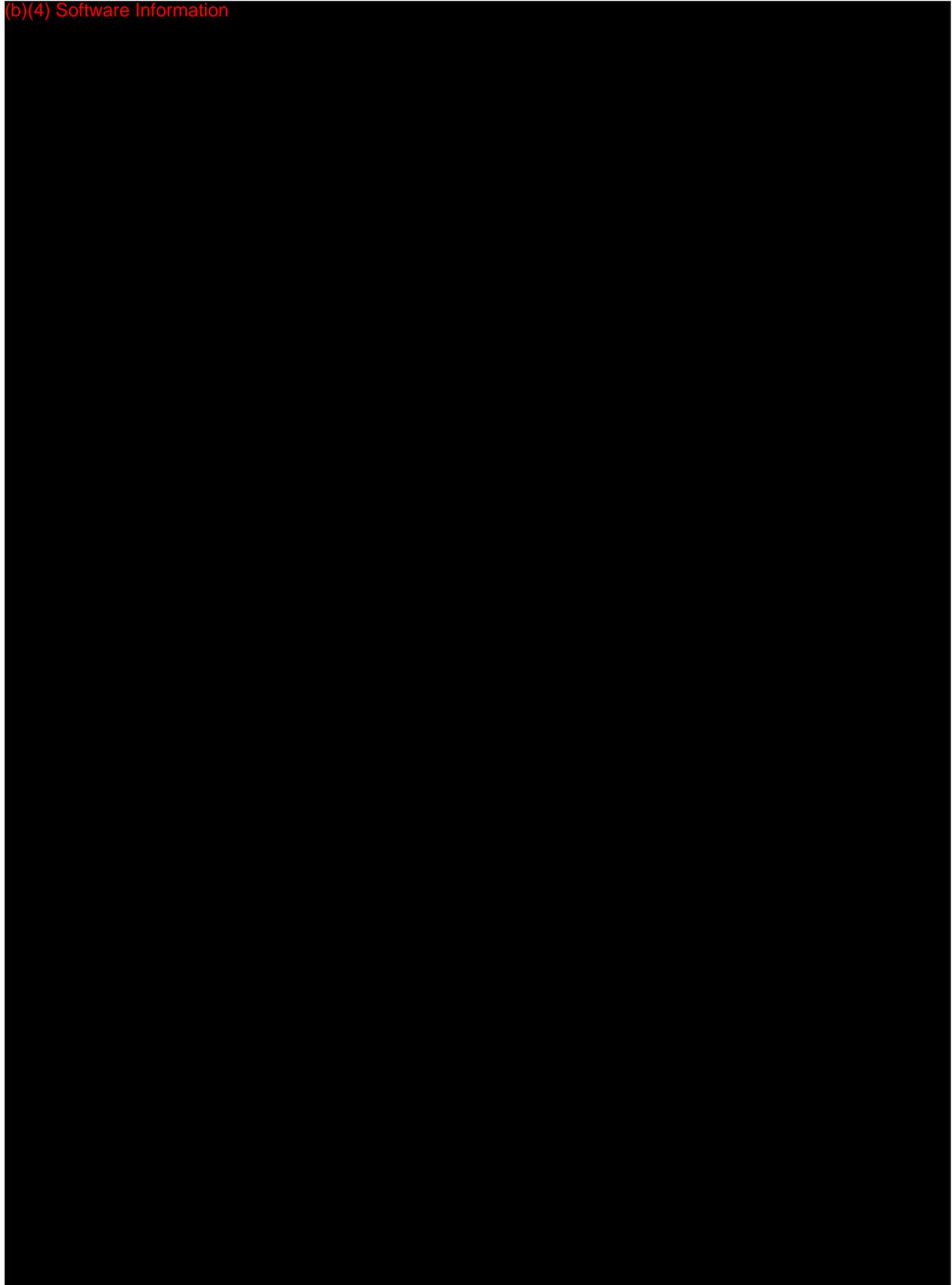
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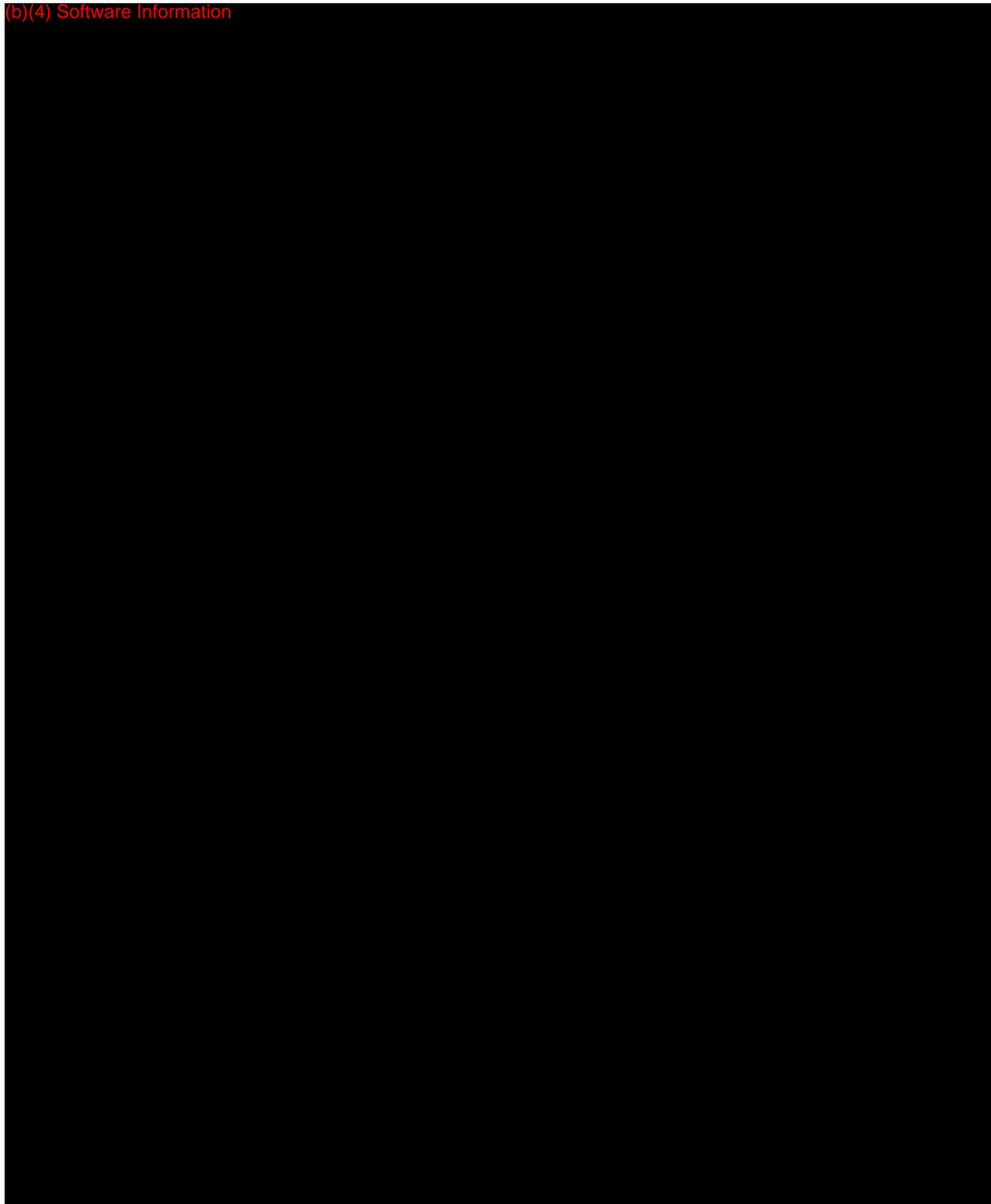


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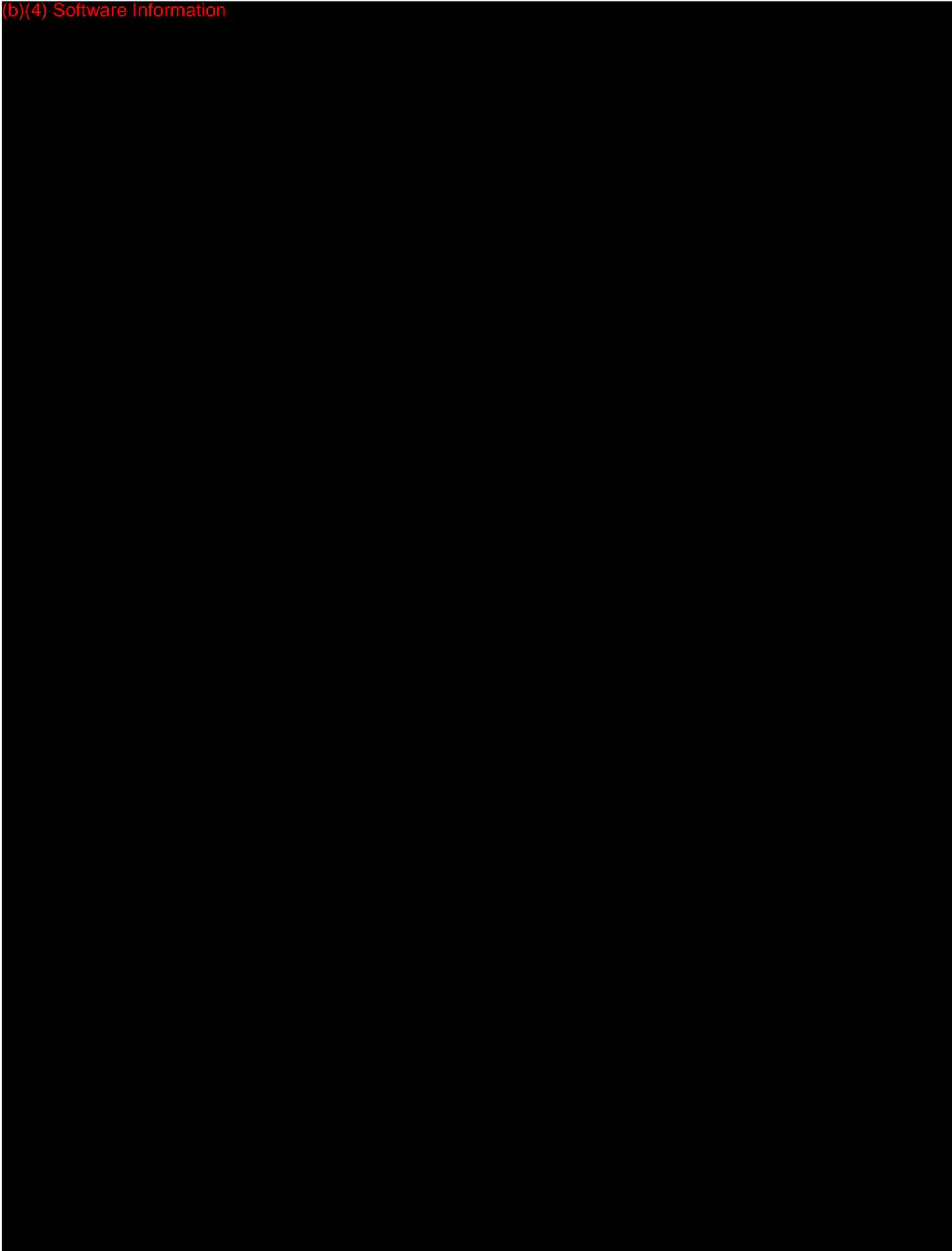
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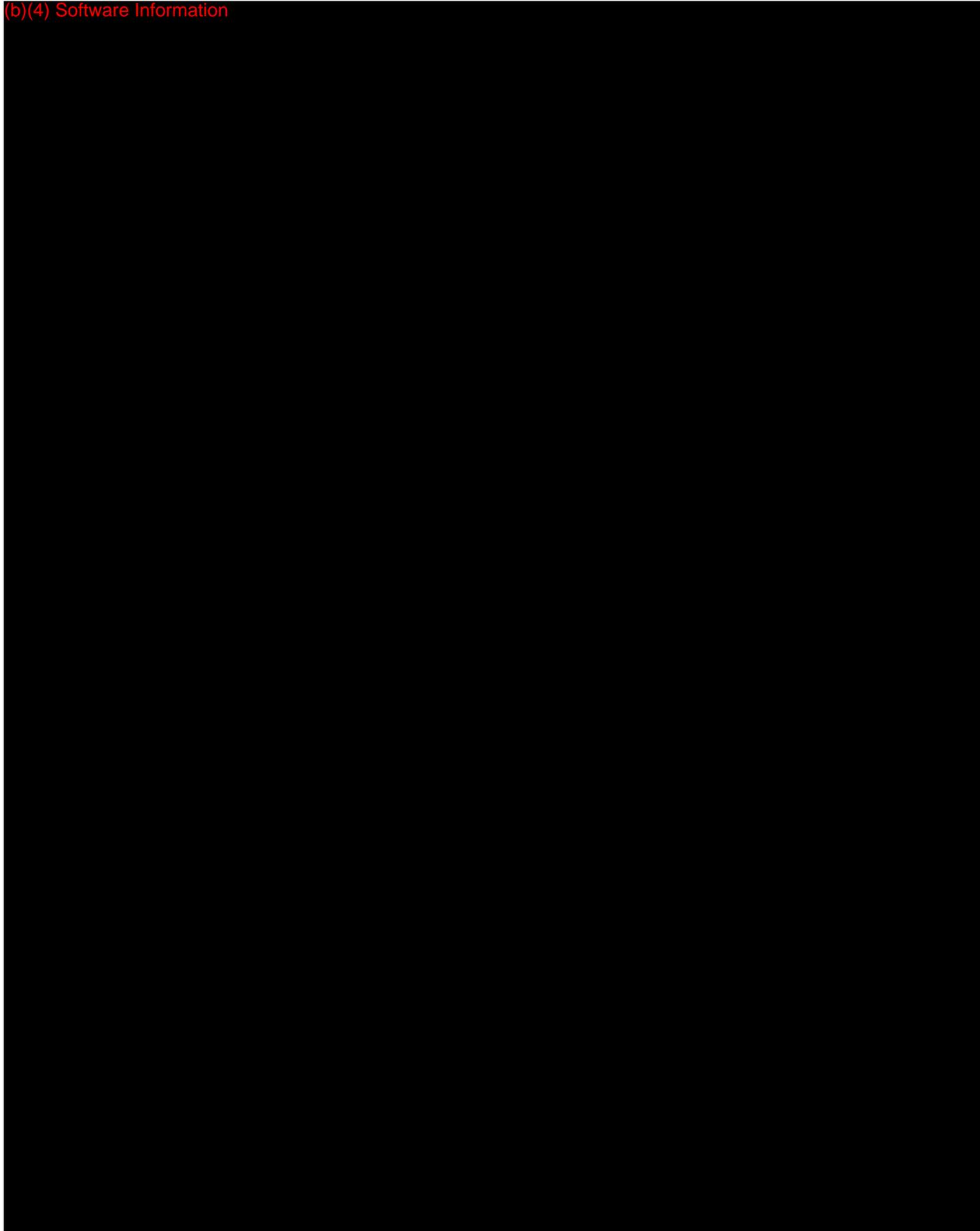


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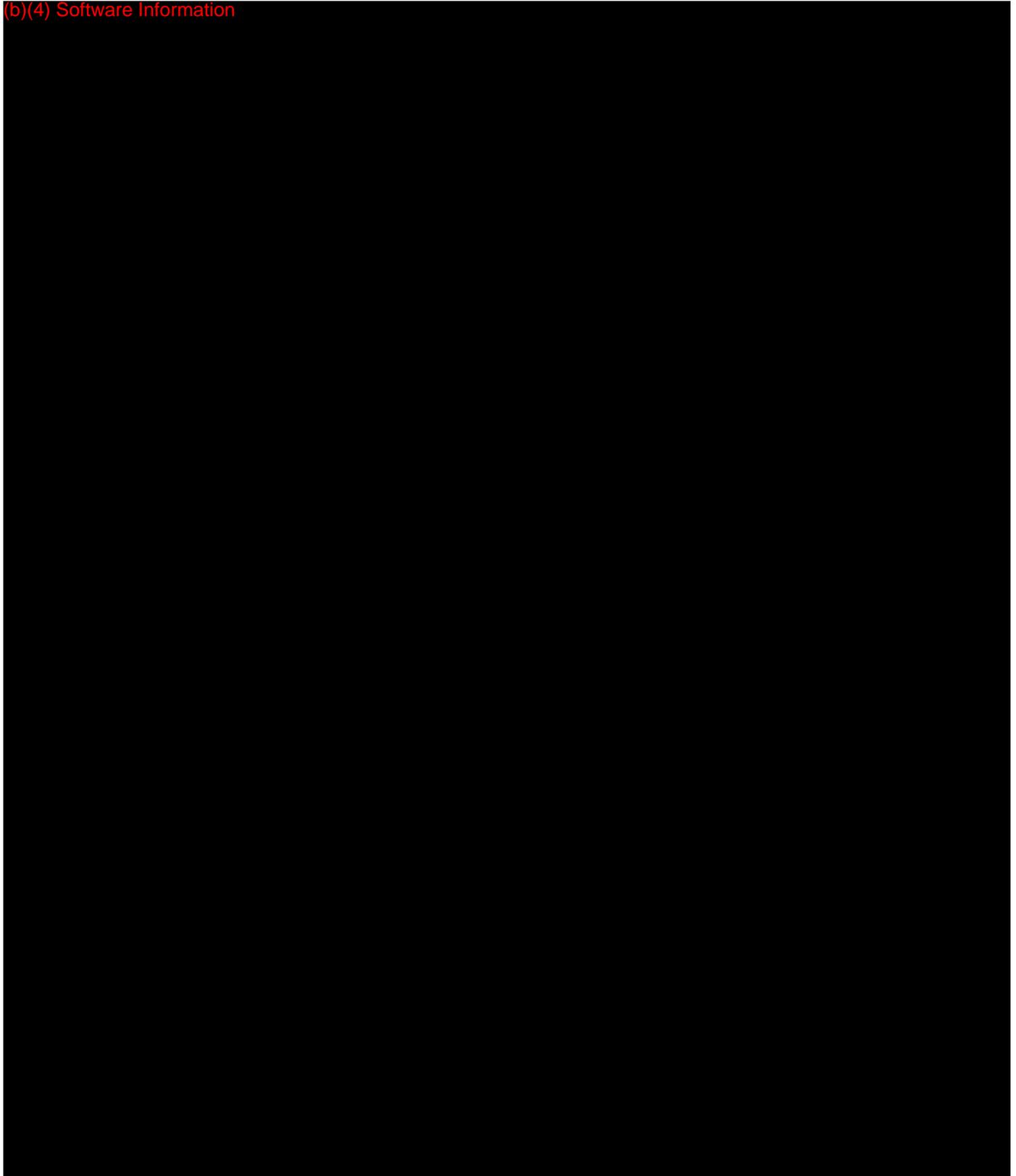


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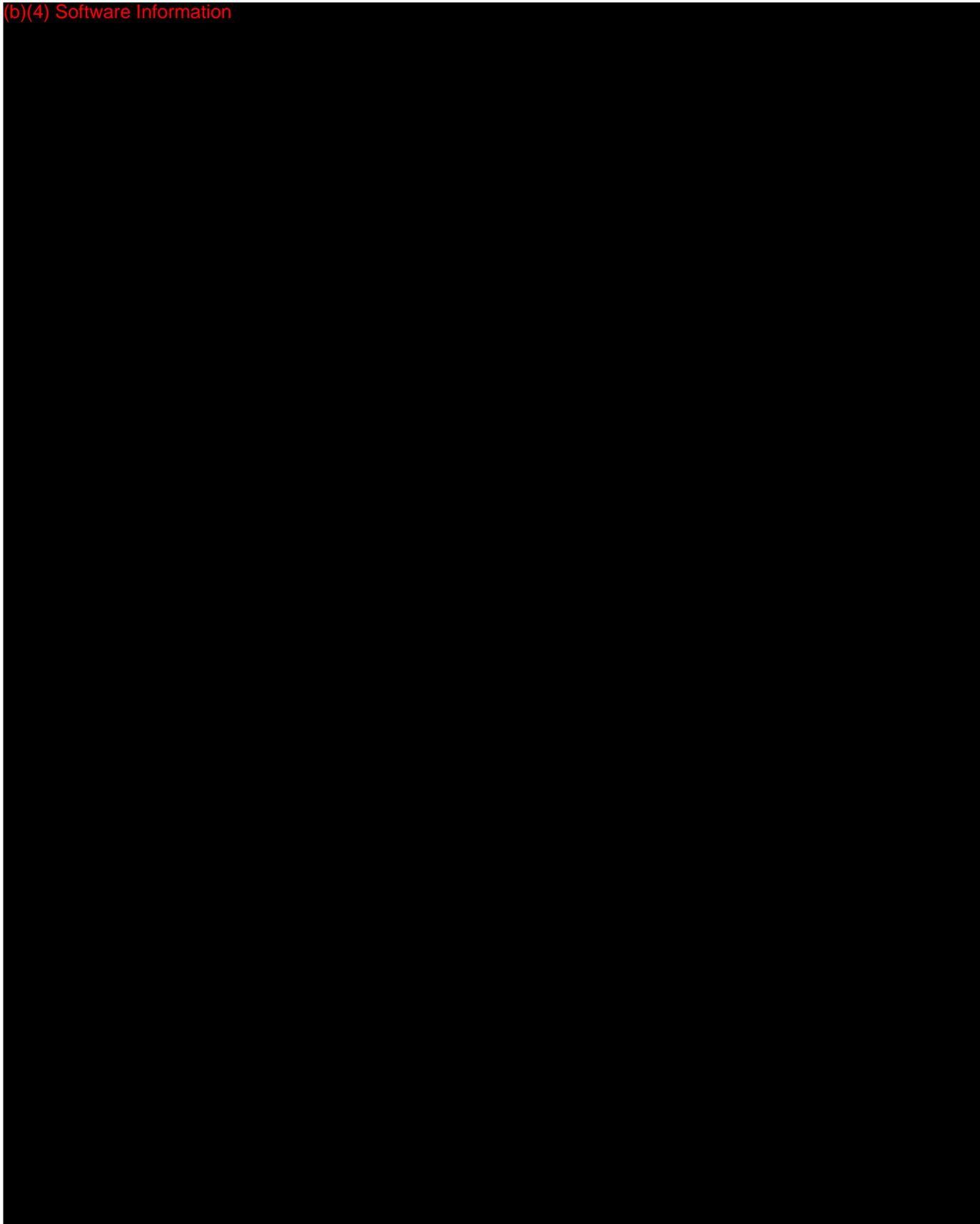
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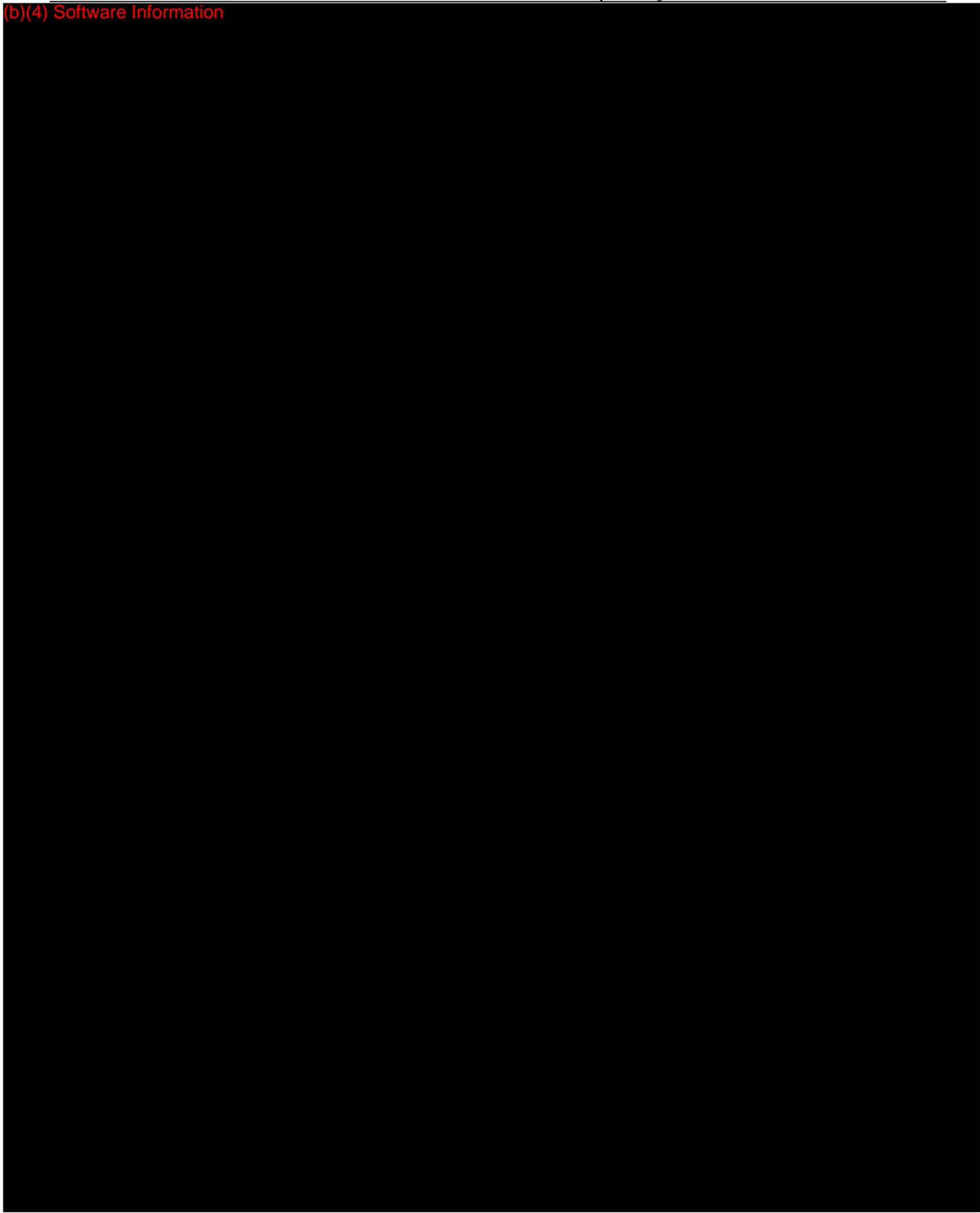
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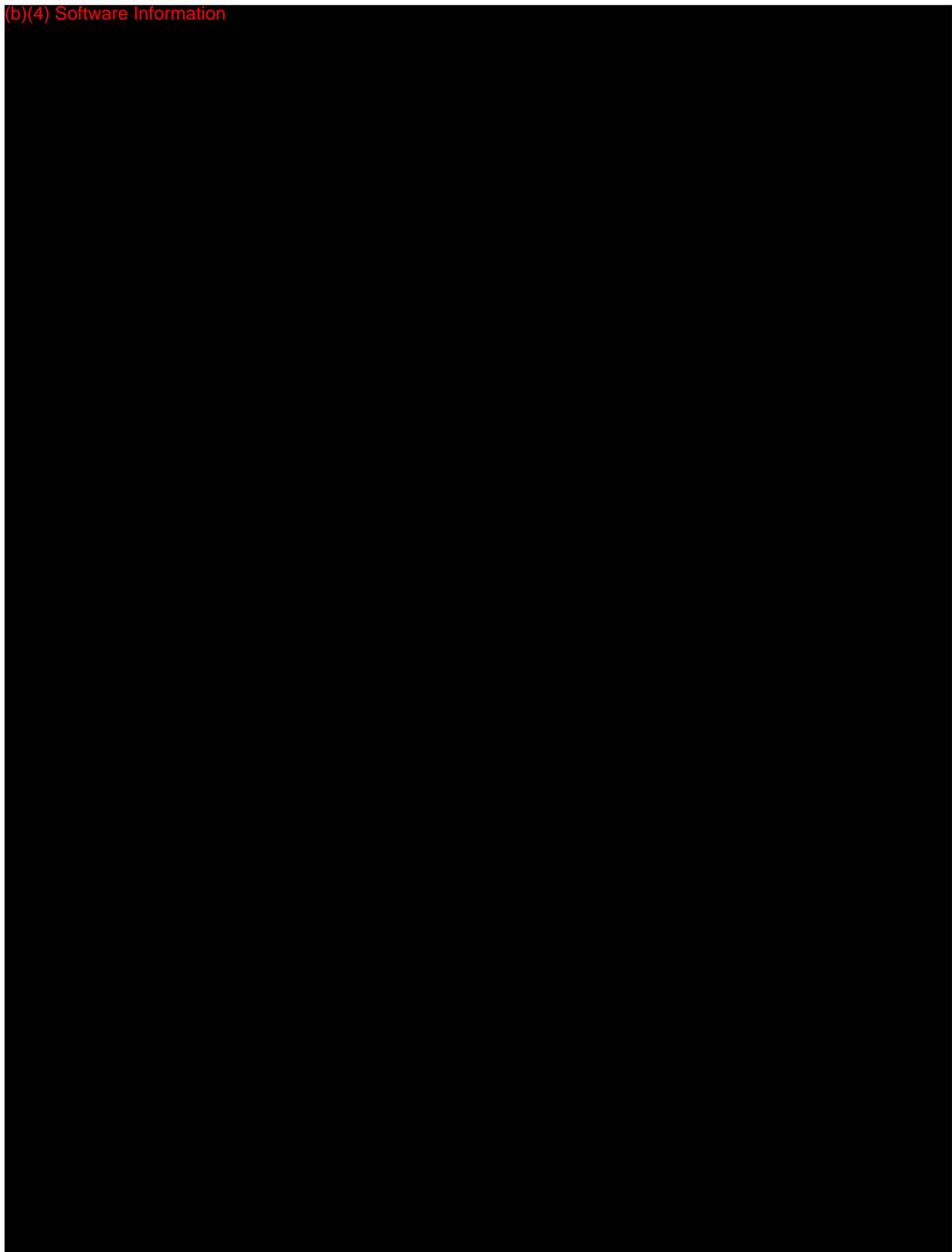
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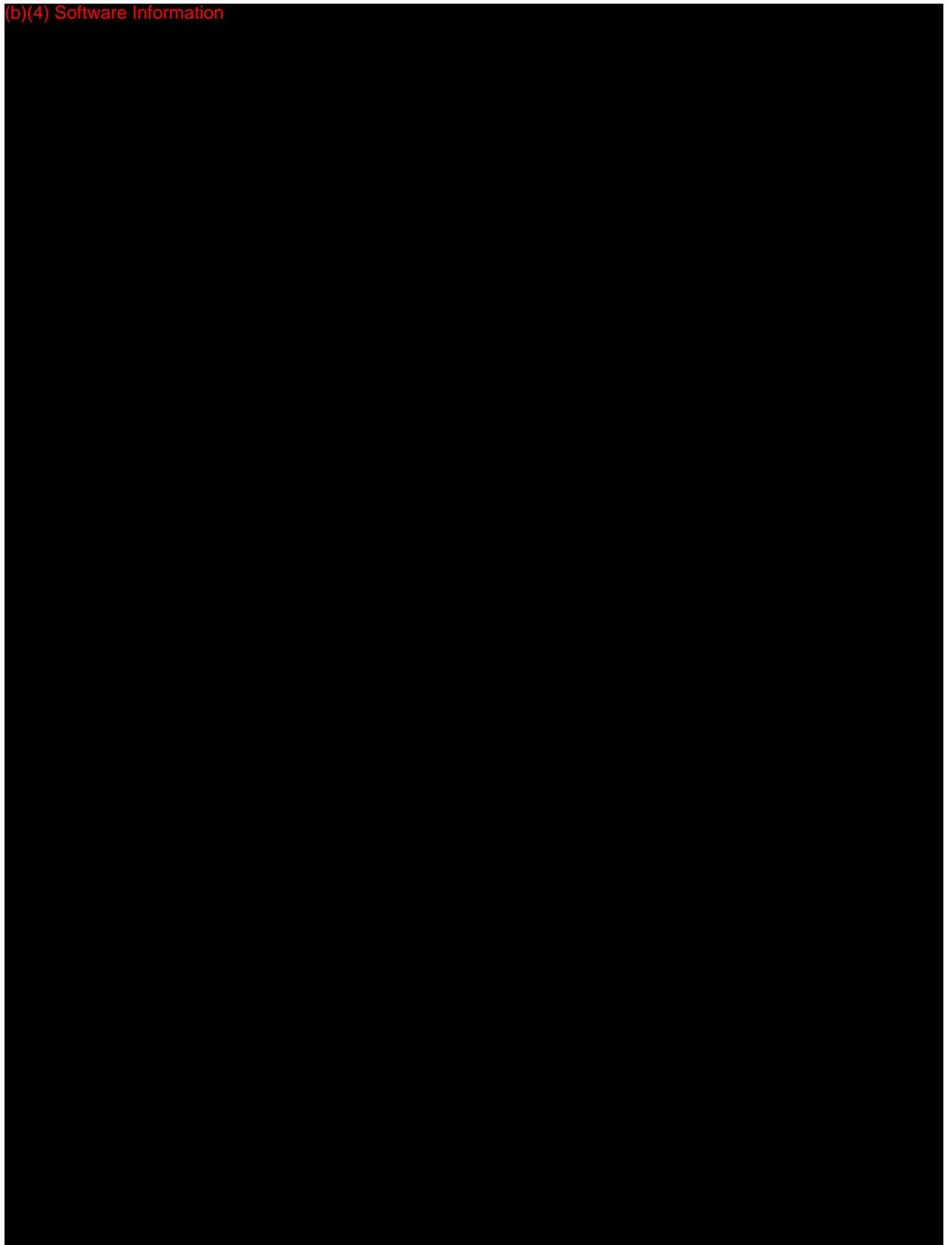


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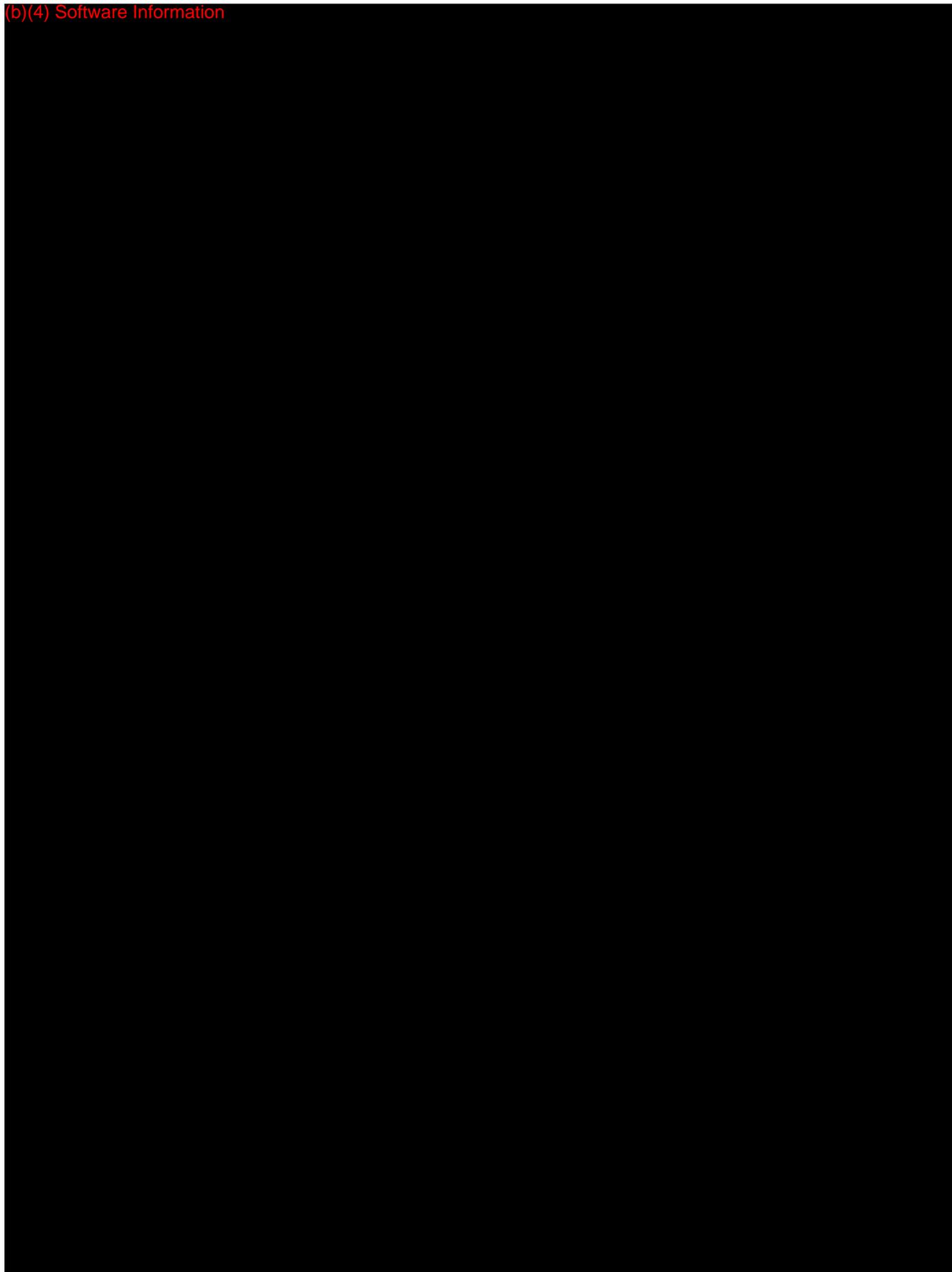


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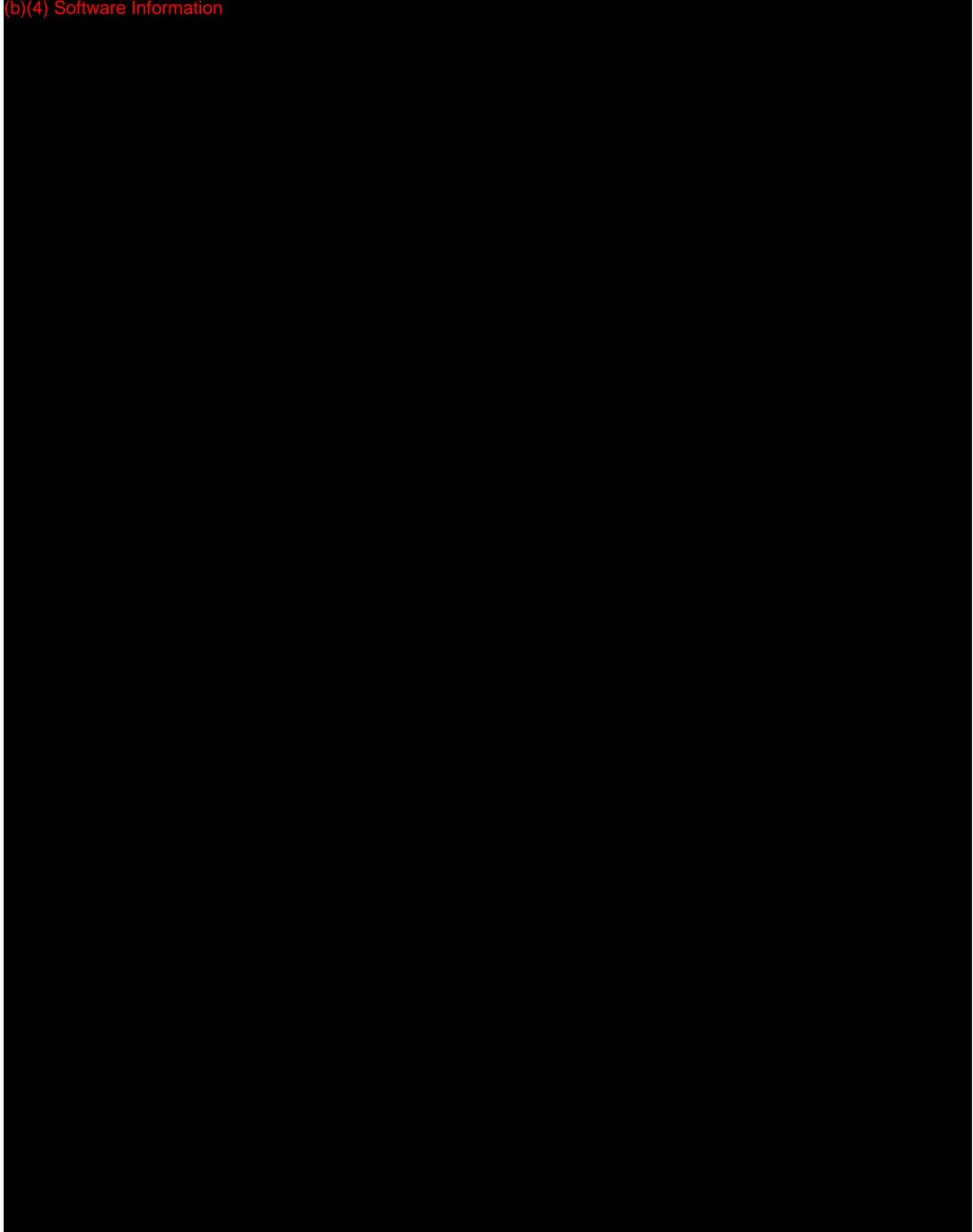


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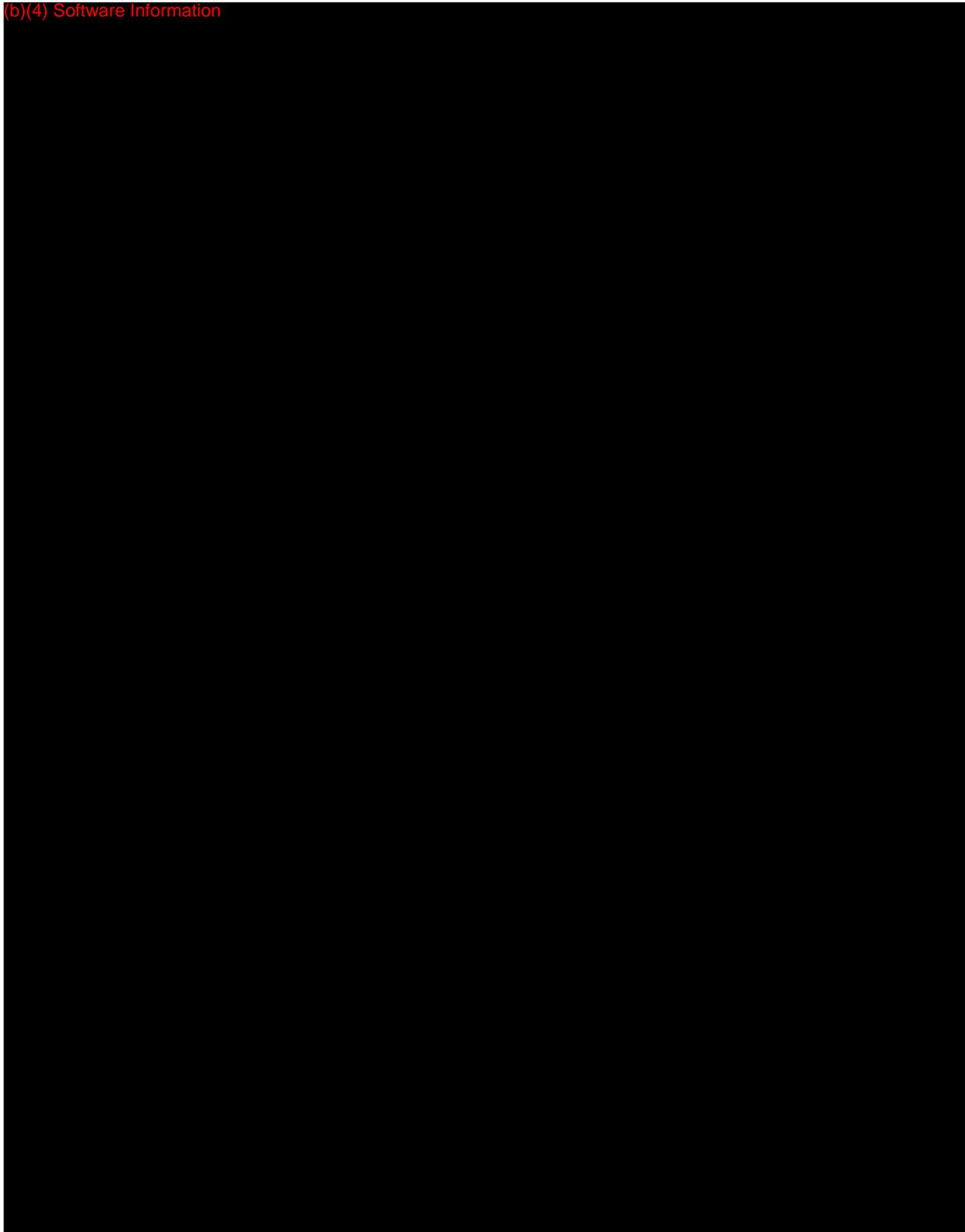


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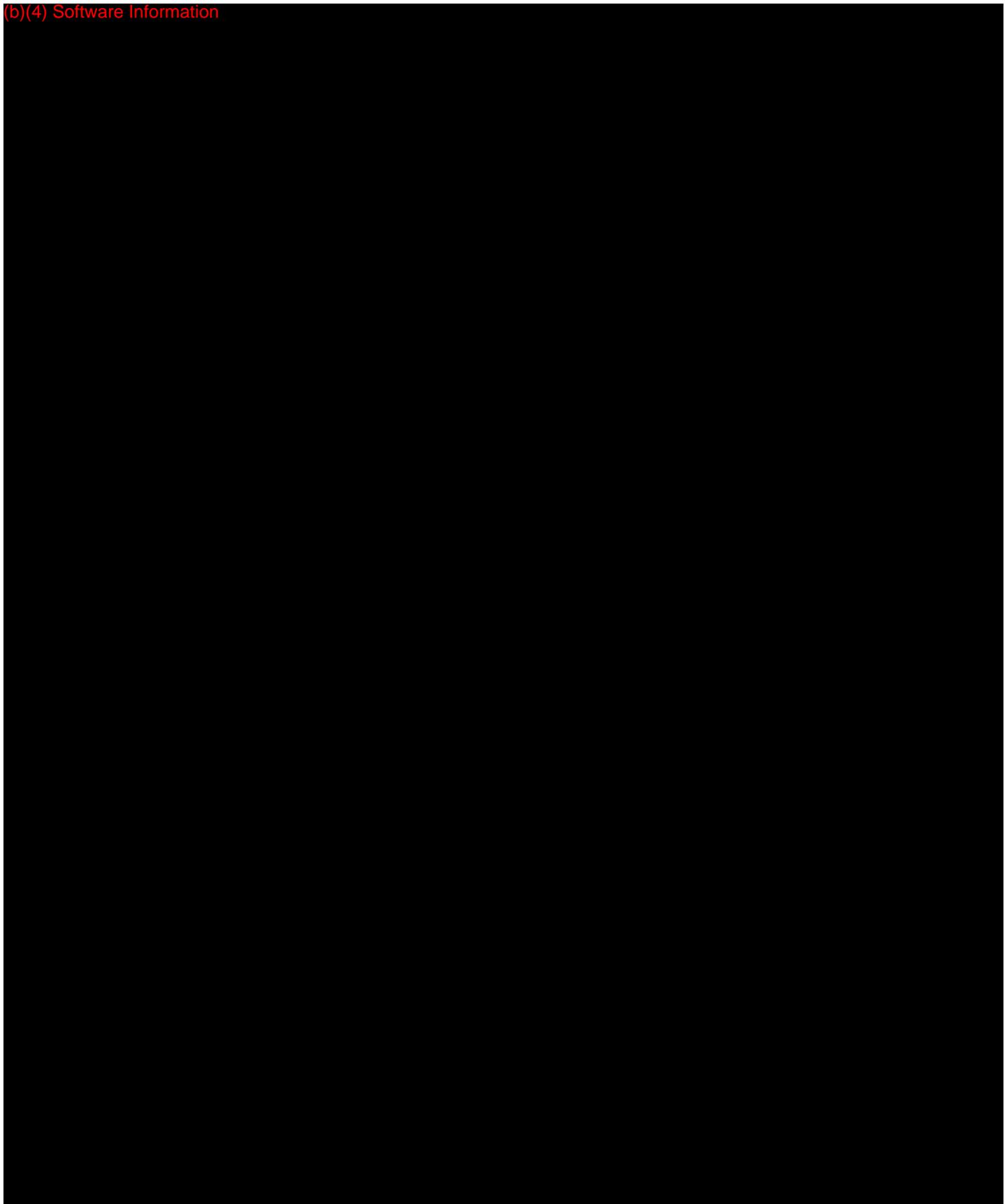
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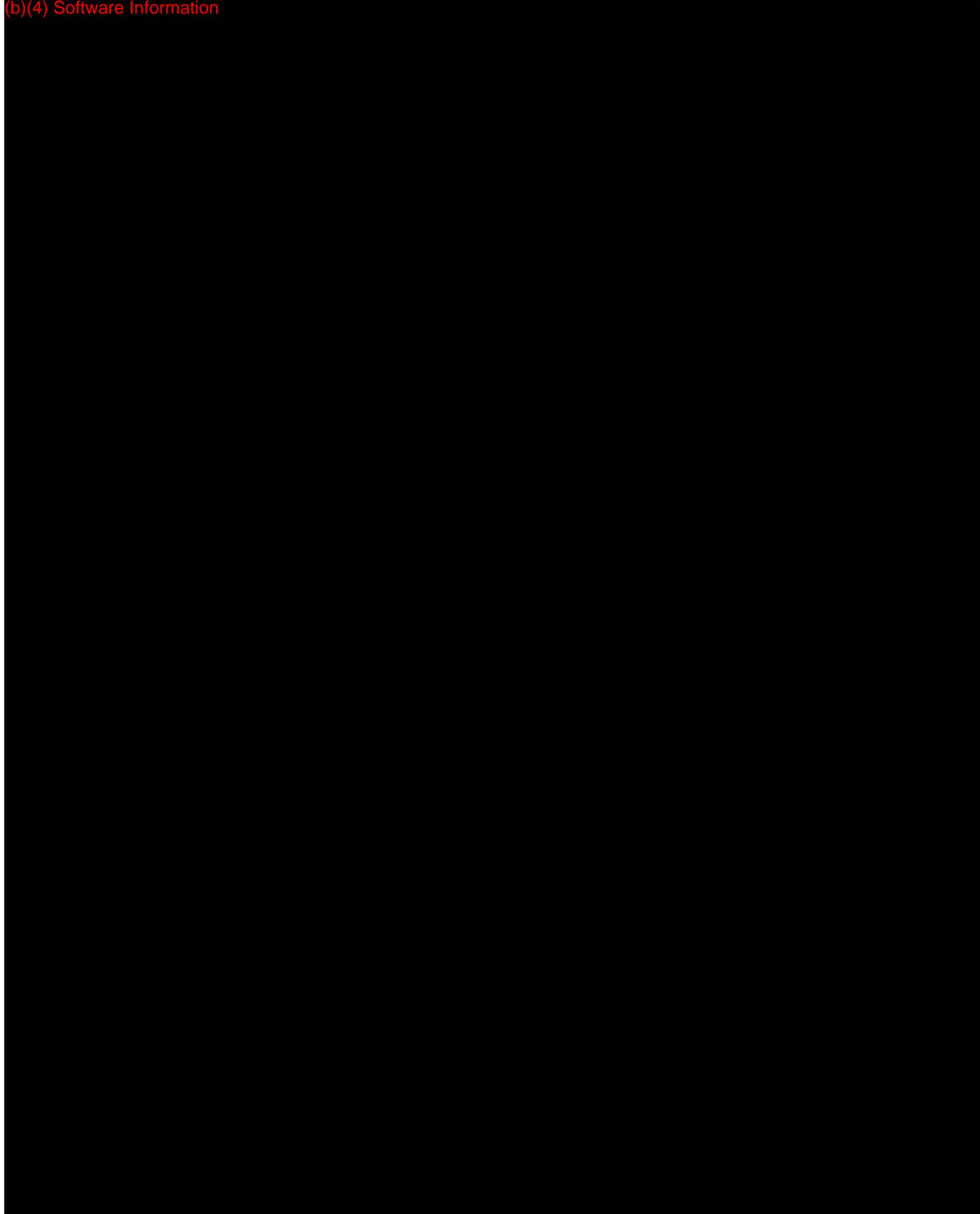


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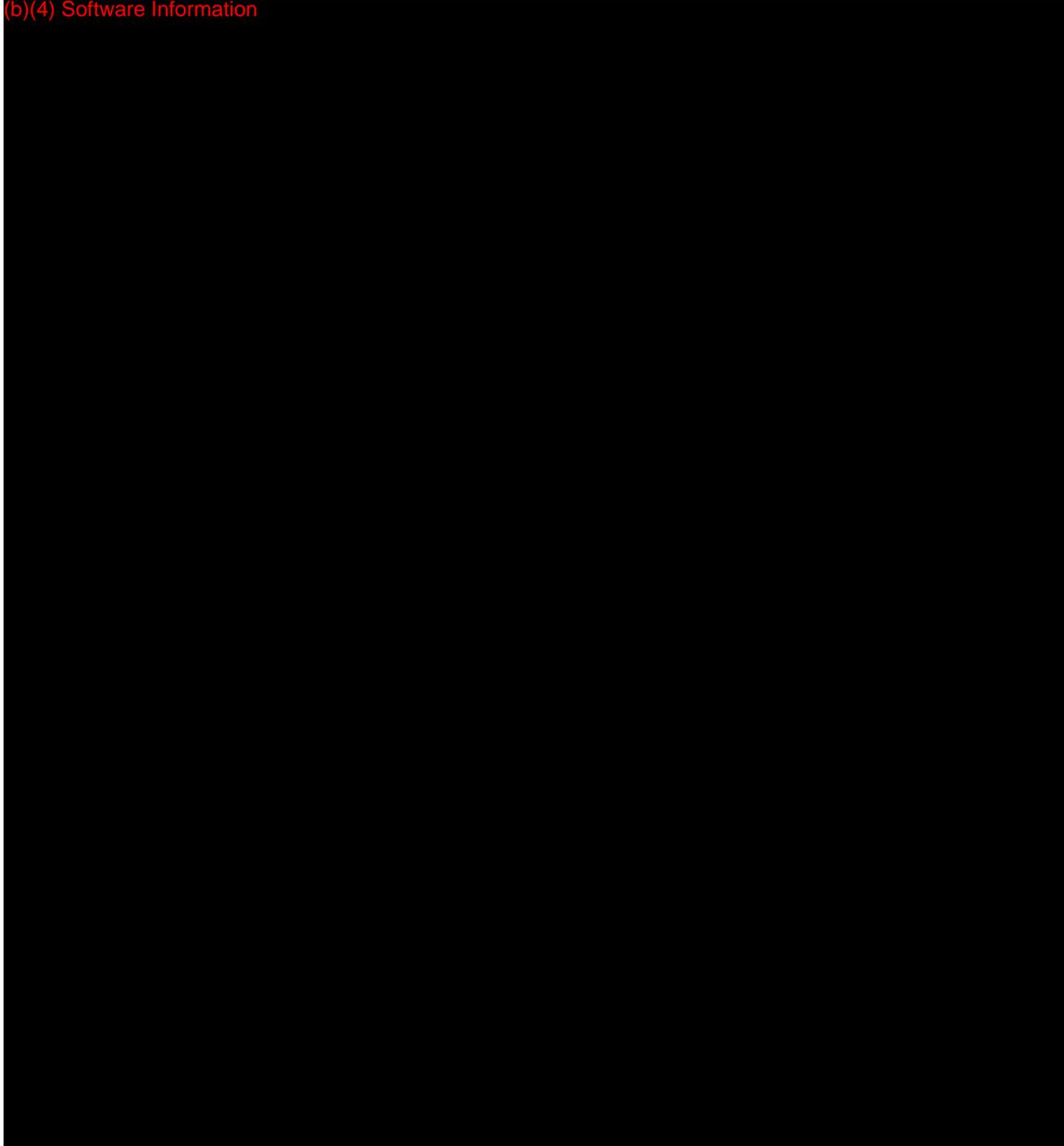


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ATTACHMENT 8-3

Software (b)(4) Software Information (b)(4) Software Information

REVISION HISTORY

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(b)		(b)(4) Software	23 Jan 2012	(b)

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FCTN	Title	Name	Signature	Date	ST. JUDE MEDICAL MORE CONTROL. LESS RISK.		St. Jude Medical MediGuide Navigation System Advanced Technology Center P.O.B 15003, Haifa 31053, Isr
(b)(4) Software Information	SW Dir	(b)(6)	[Redacted Signature]	23 JAN. 12	TITLE	(b)(4) Software Information	(b)(4) Software (b)(4)
	S.T. Leader			23/1/12			
	Proj Dir			23.1.12			
	QA Dir			23 Jan 2012			
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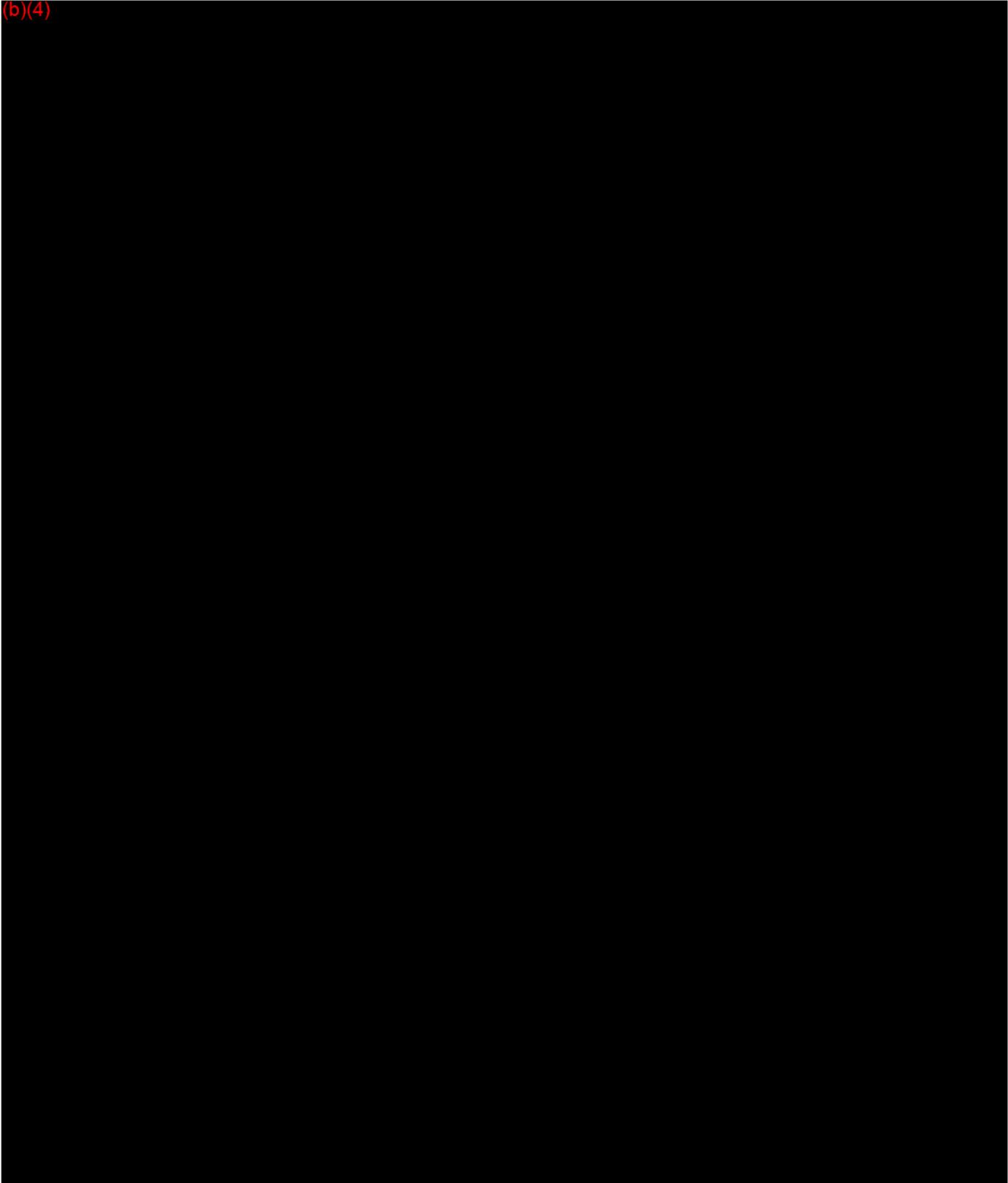
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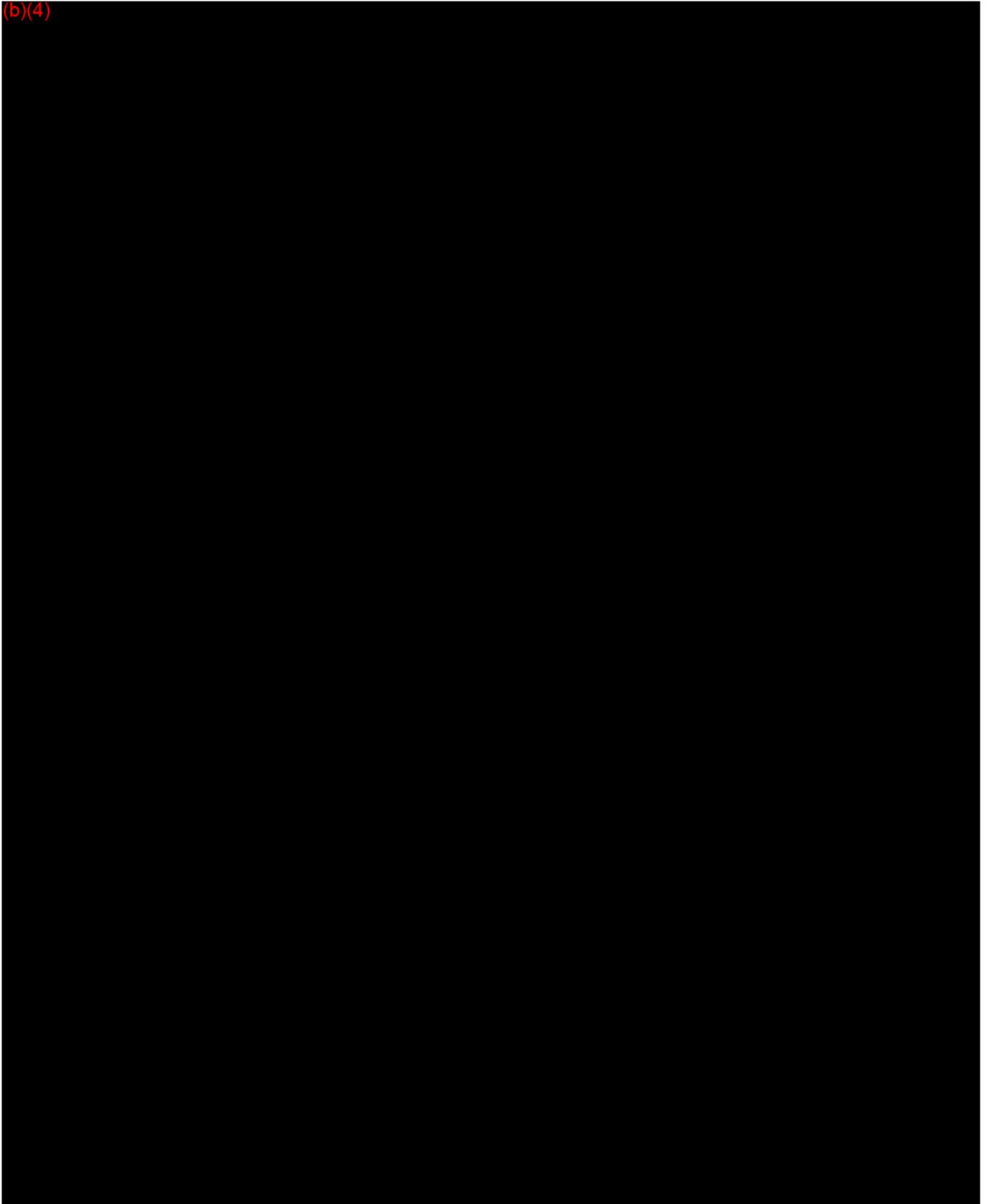
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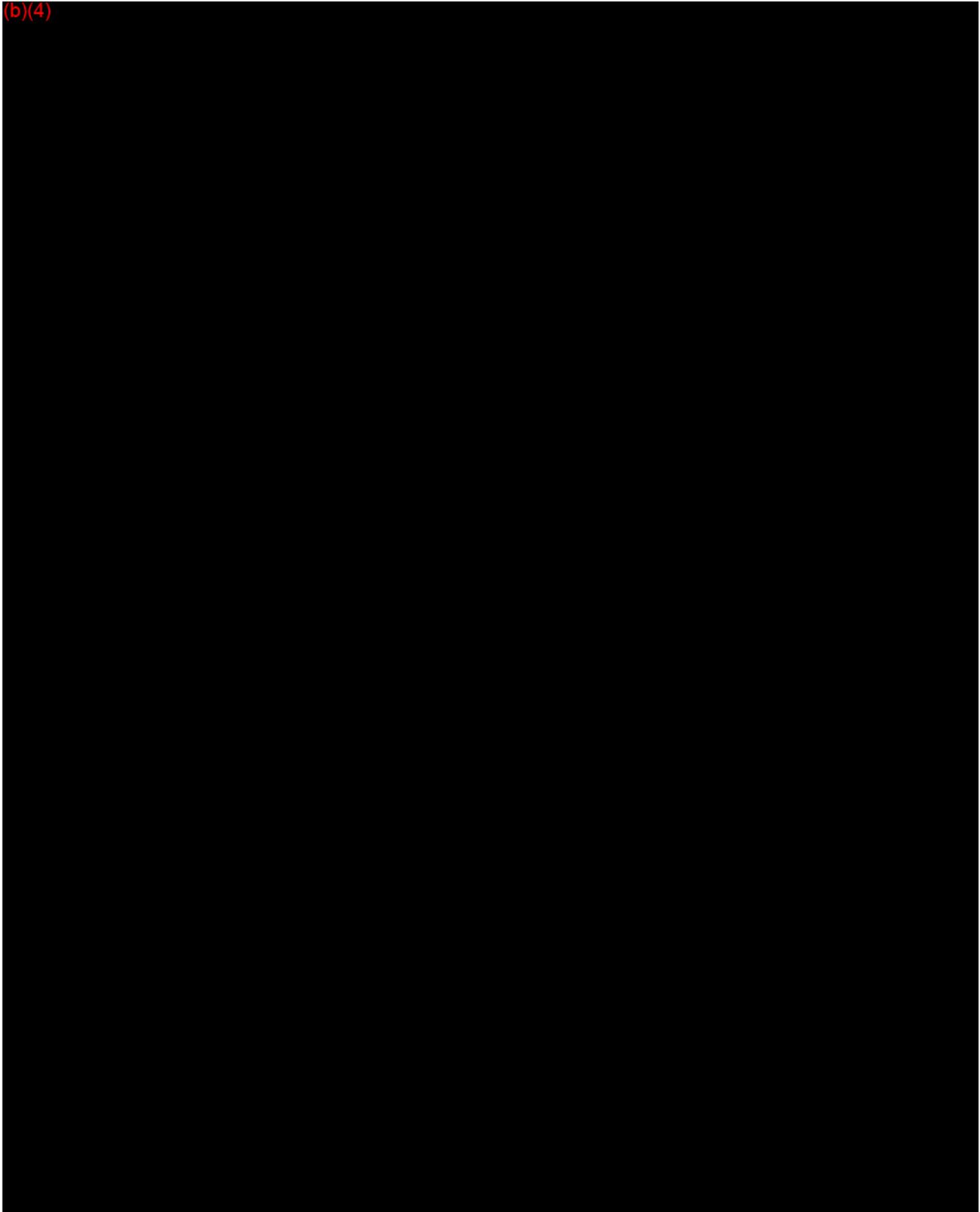
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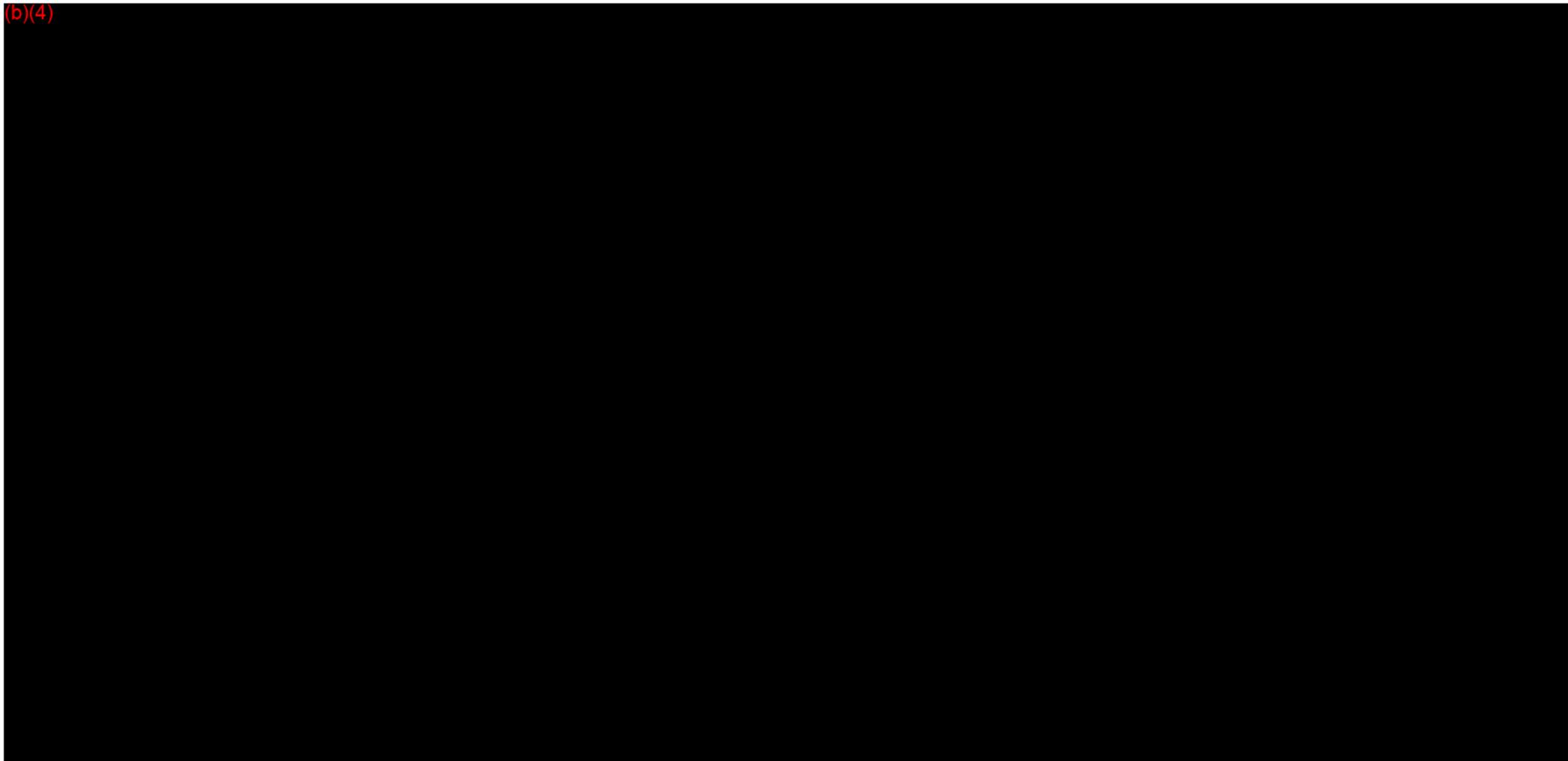


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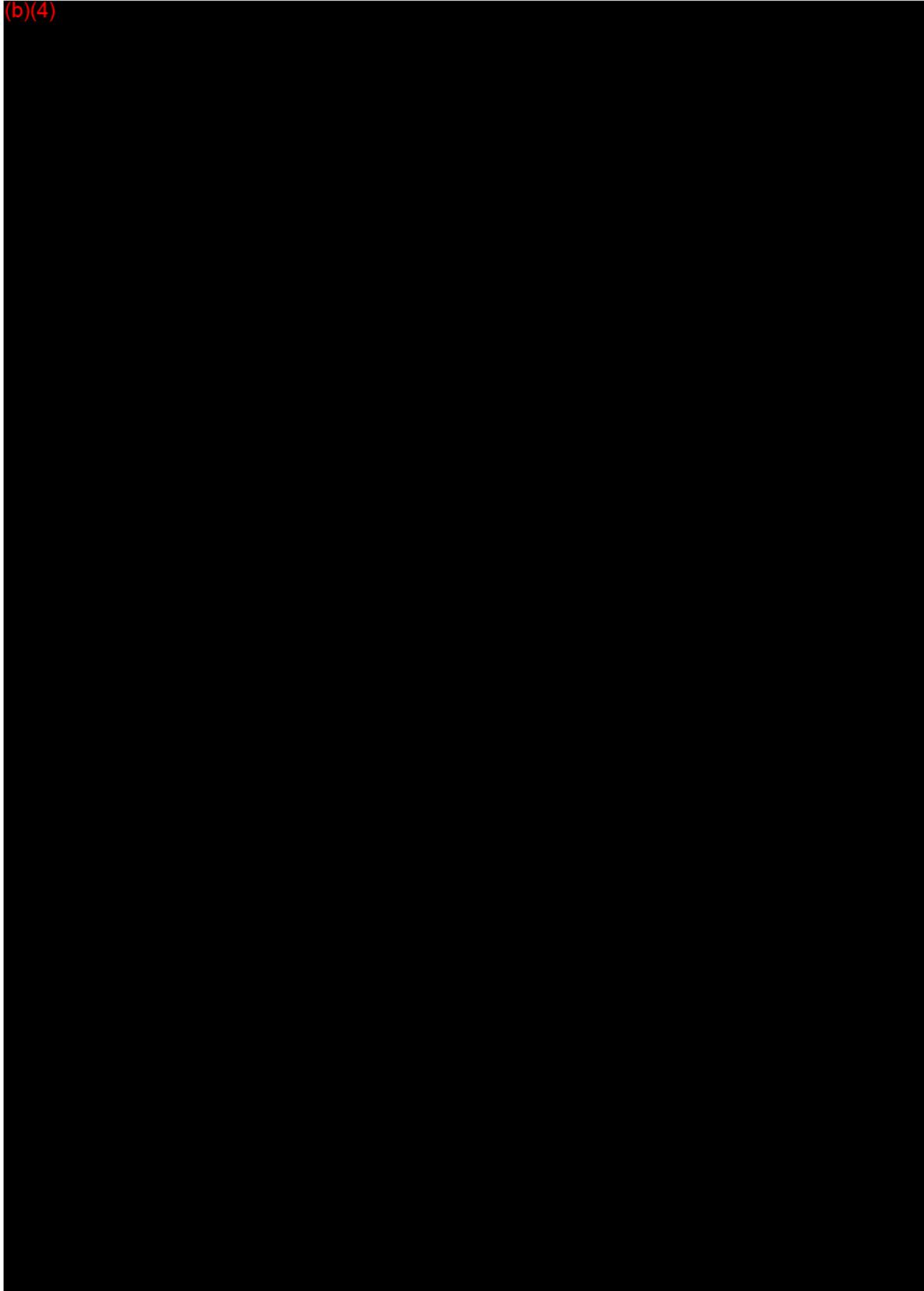
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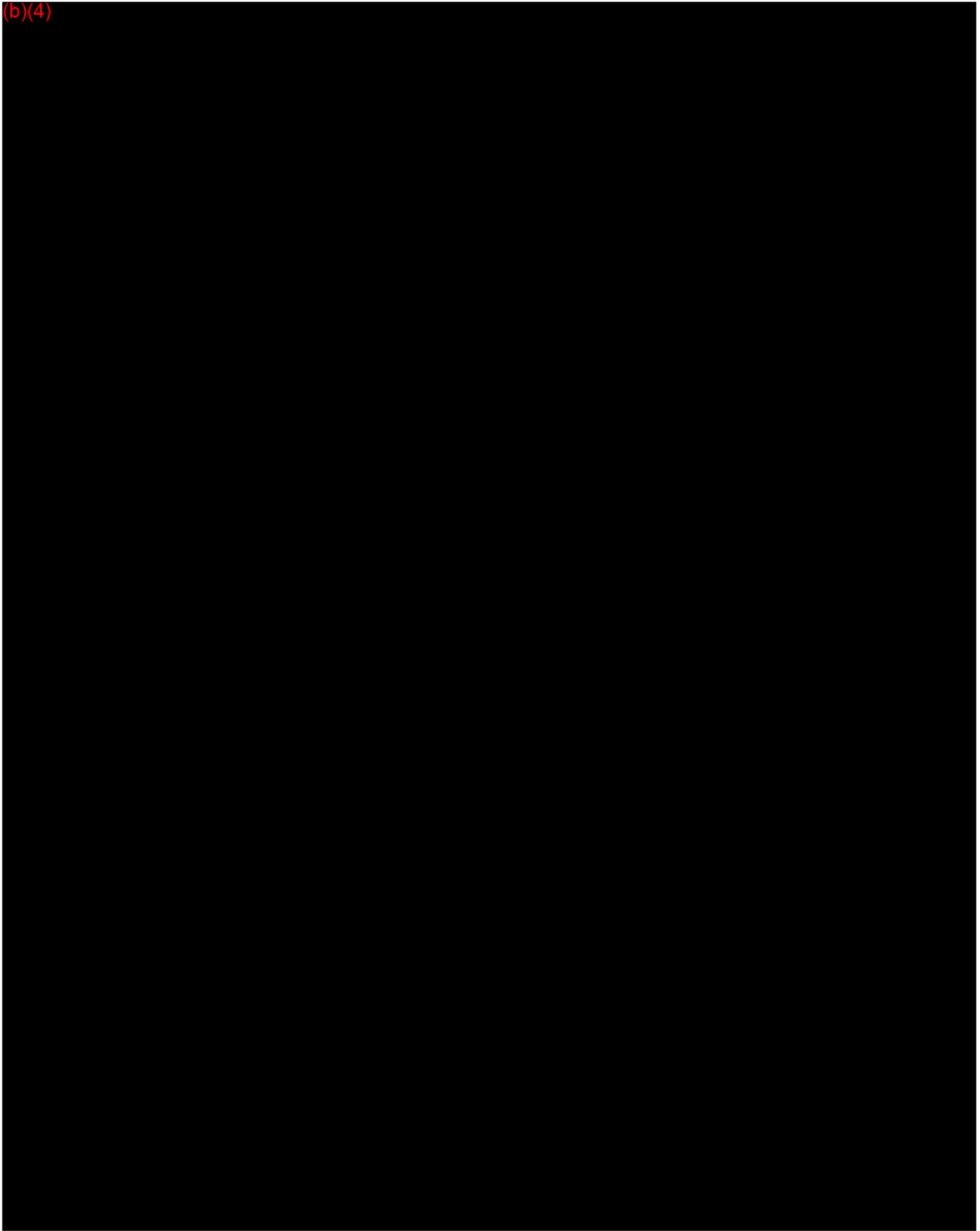
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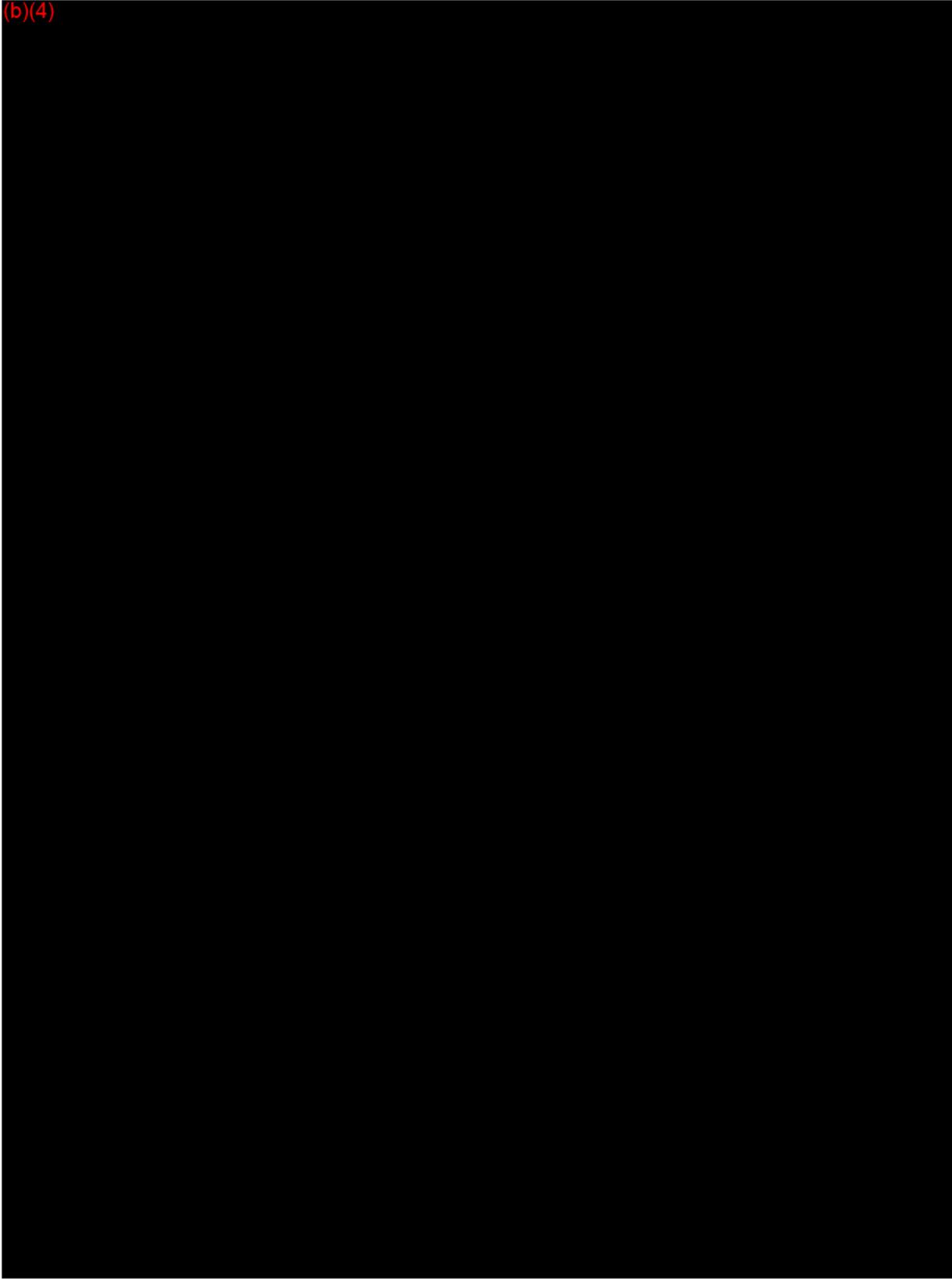
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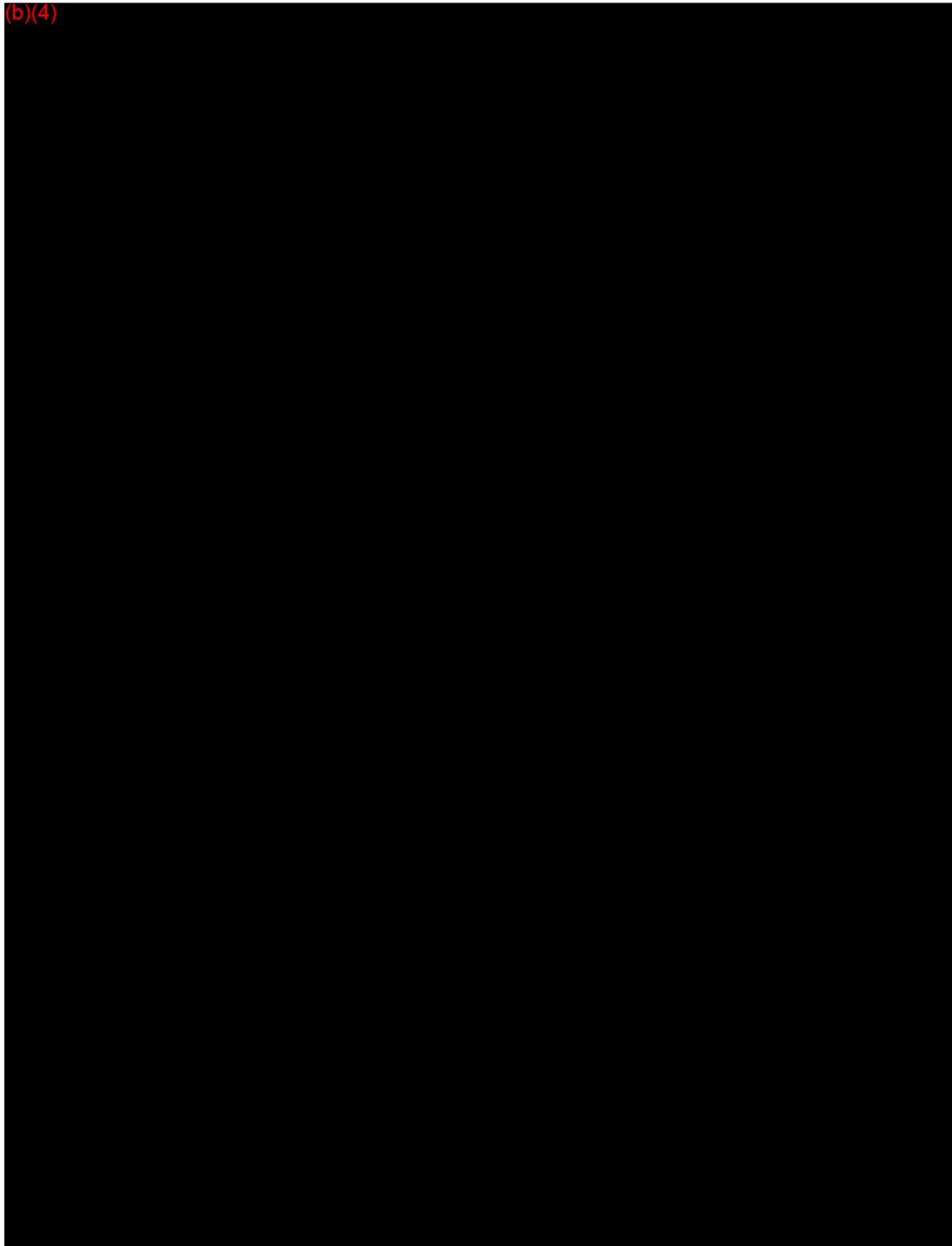
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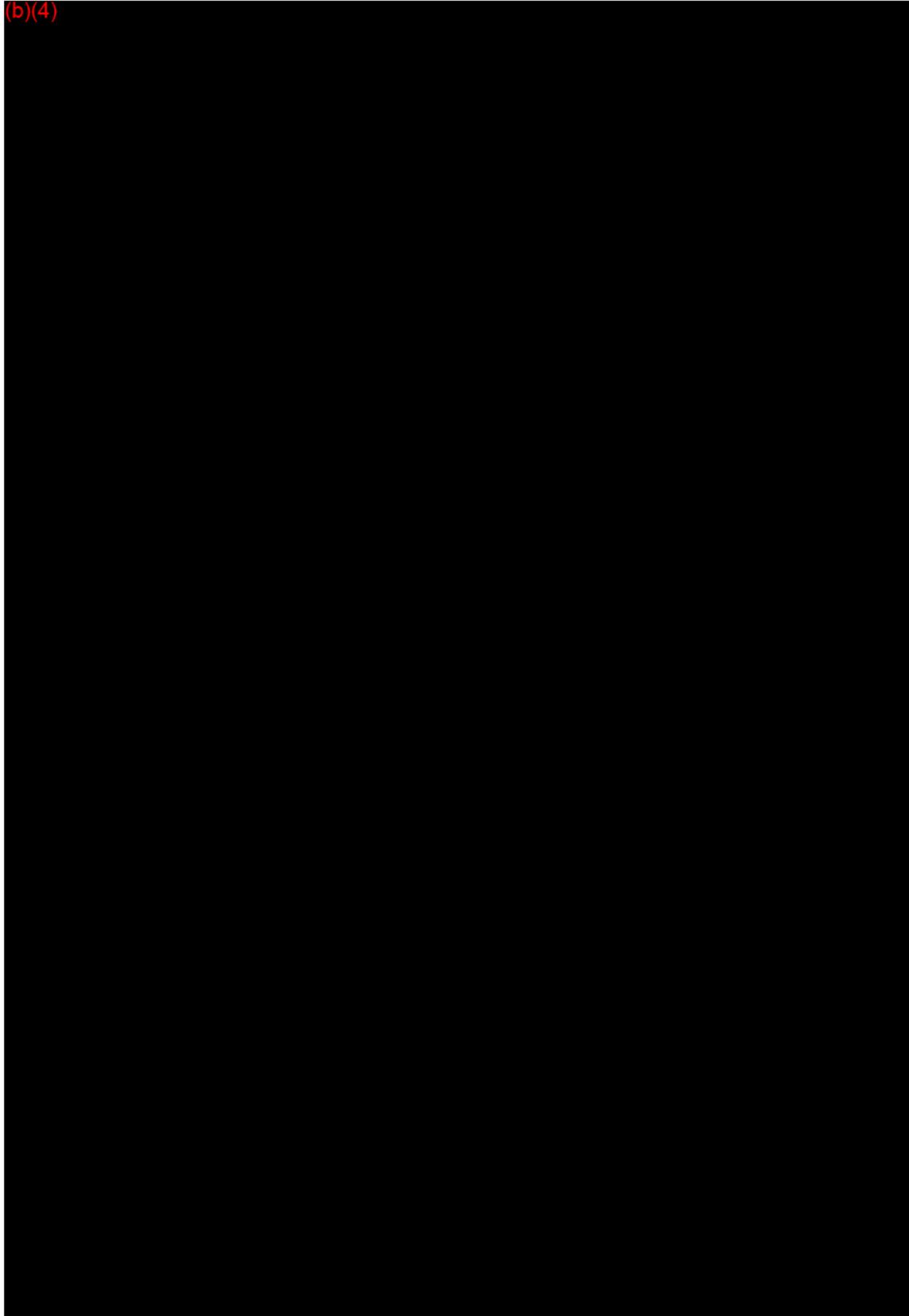
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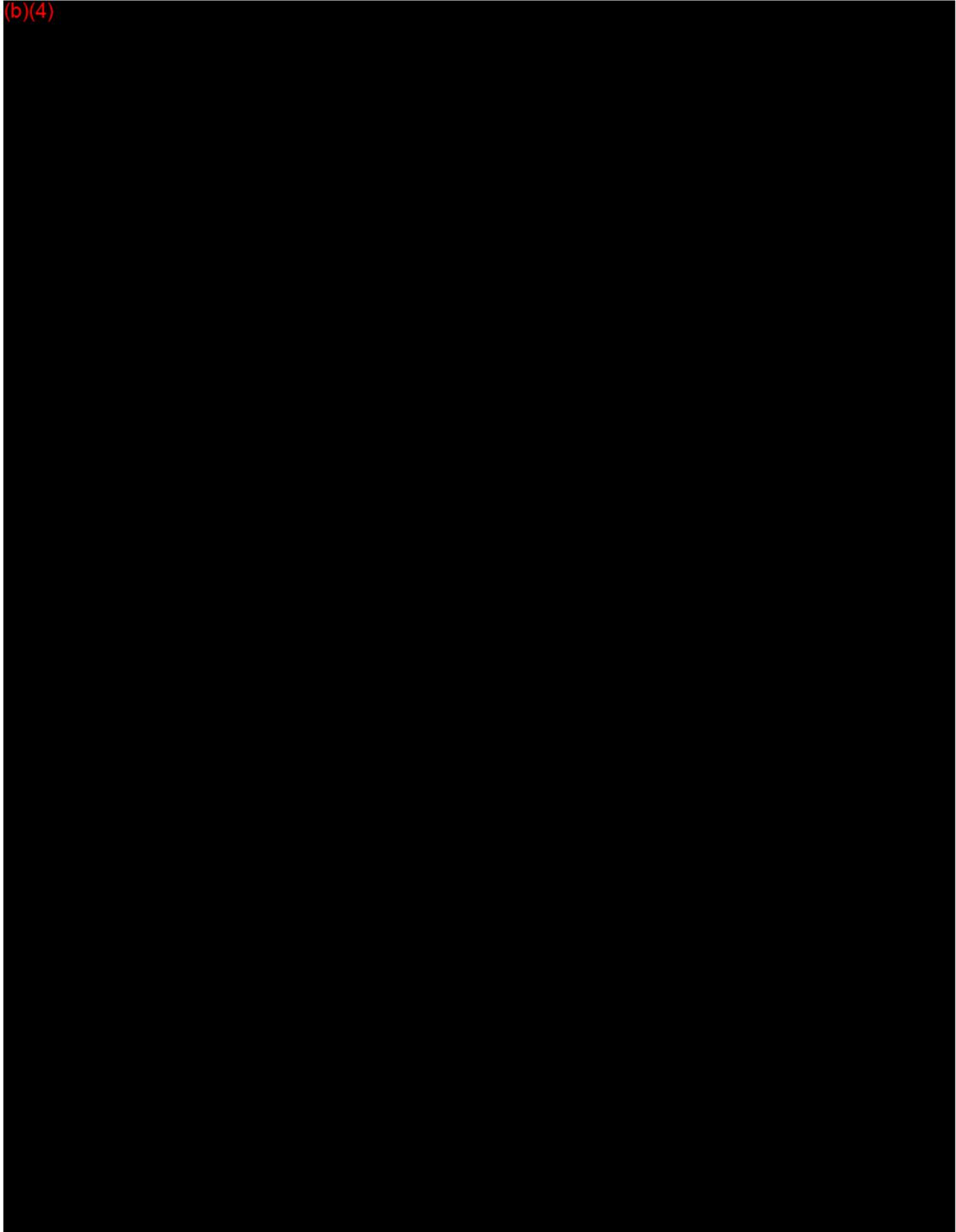
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ATTACHMENT 8-4

Software (b)(4) Software Information

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REVISION HISTORY				
REV	CHG NO	DESCRIPTION	DATE	APPROVED
(b)(4)		(b)(4)	30 Apr 2011	(b)(4)
(b)(4)		(b)(4)	1 Nov 2011	(b)(4)
(b)(4)		(b)(4)	4 Jan 2012	(b)(4)

DISTRIBUTION LIST		
COPY	NAME	TITLE / DEPARTMENT
(b)(4)	(b)(4) Software	Quality Assurance
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PROGRAM NAME: gCRM

ALL SHEETS ARE THE SAME REVISION

		(b)(6)				
FCTN	TITLE		DATE	ST. JUDE MEDICAL <small>ST. JUDE MEDICAL, 1991-2012</small>	St Jude Medical MediGuide Navigation Systems ADVANCED TECHNOLOGY CENTER P.O.B 15003, HAIFA 31053, ISRAEL	
(b)(4)	SW T.L.		30.1.12		TITLE	
	Sys Eng		10/04/12		(b)(4)	
	SW Dir		29.7.12		(b)(4)	
	Prog Dir		30-1-2012		(b)(4)	
	QA Dir		30 Jan 2012	SIZE	DOC. NO.	
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				SCALE NONE	SHEET 1 OF 110	

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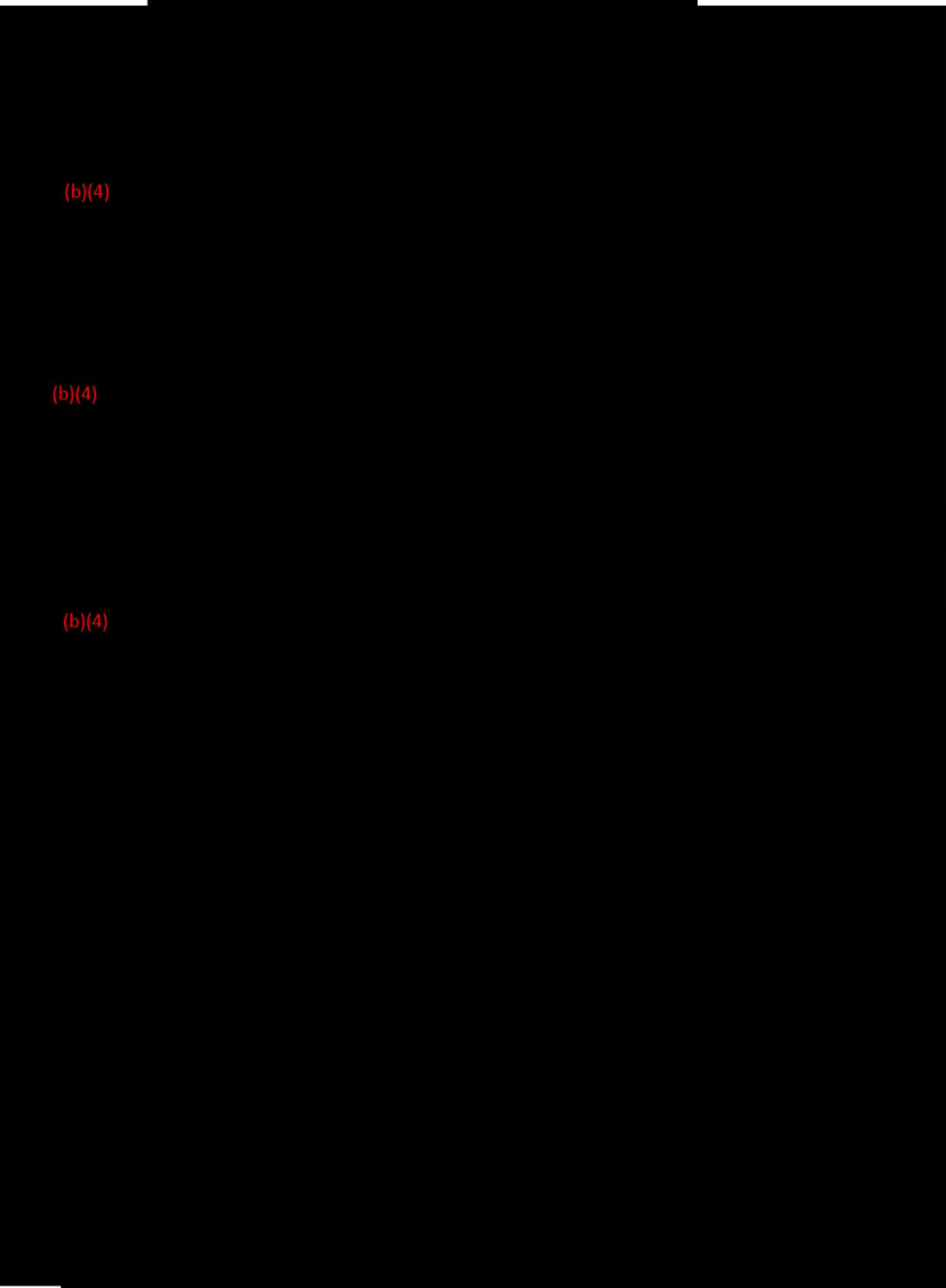


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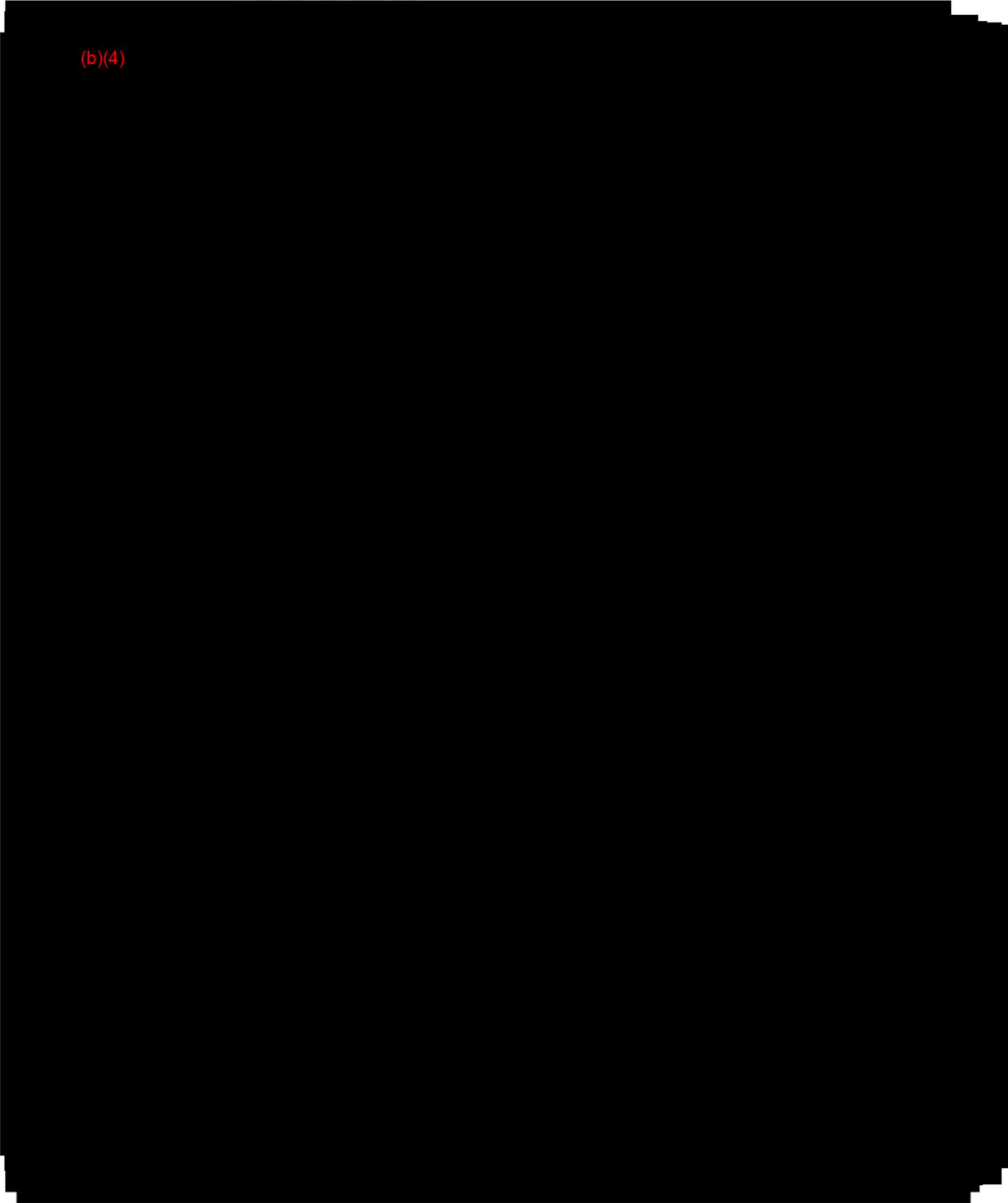
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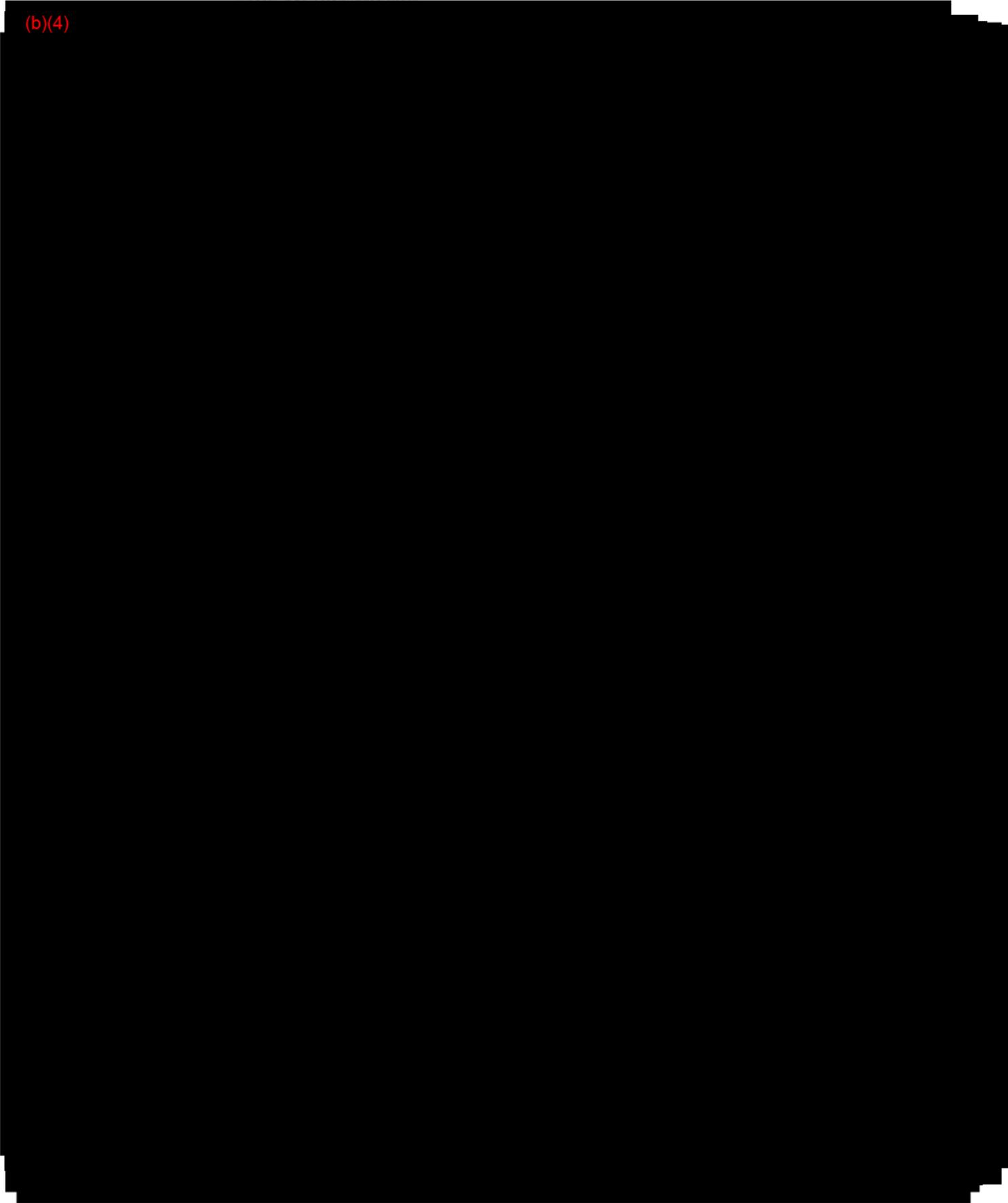
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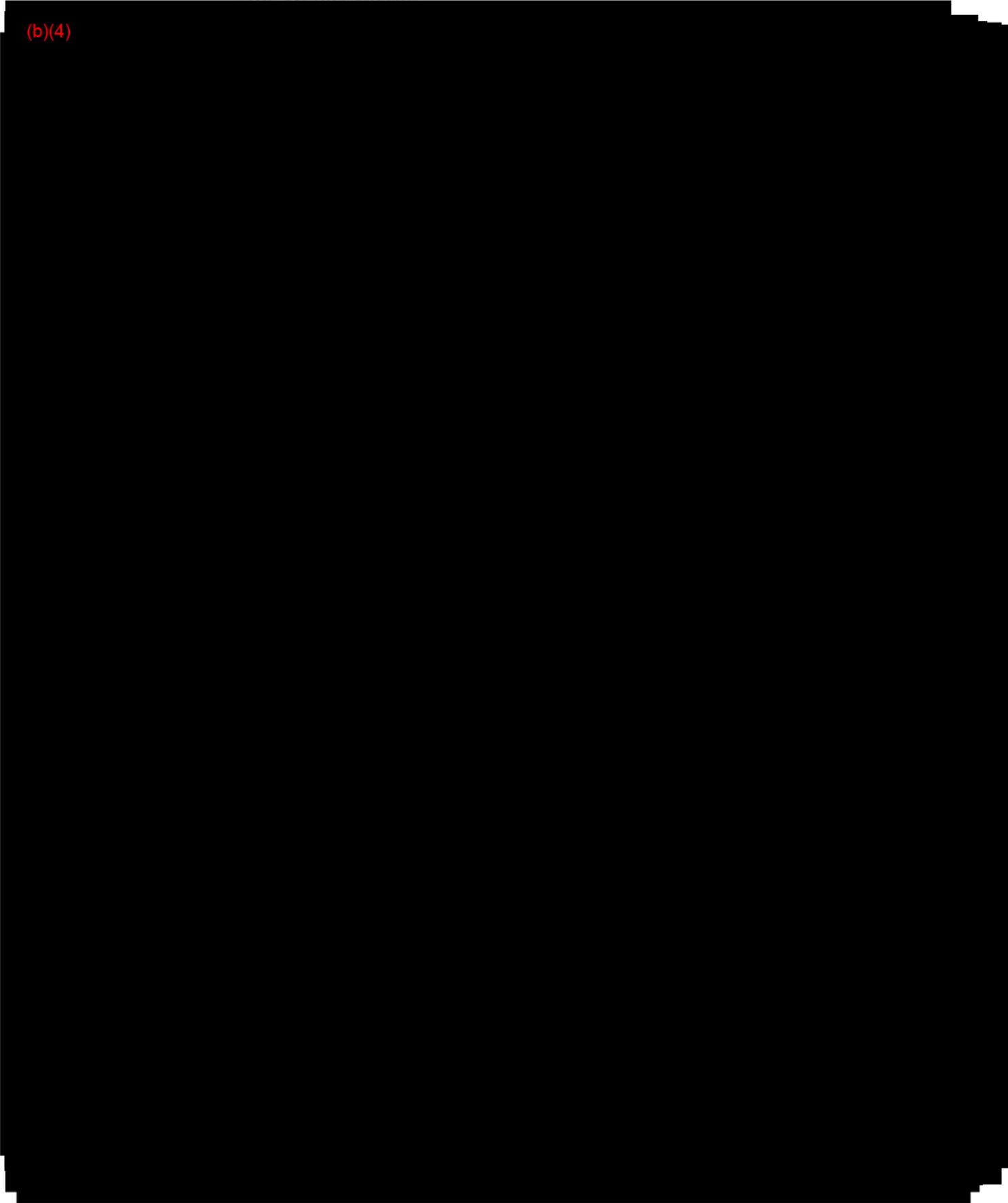
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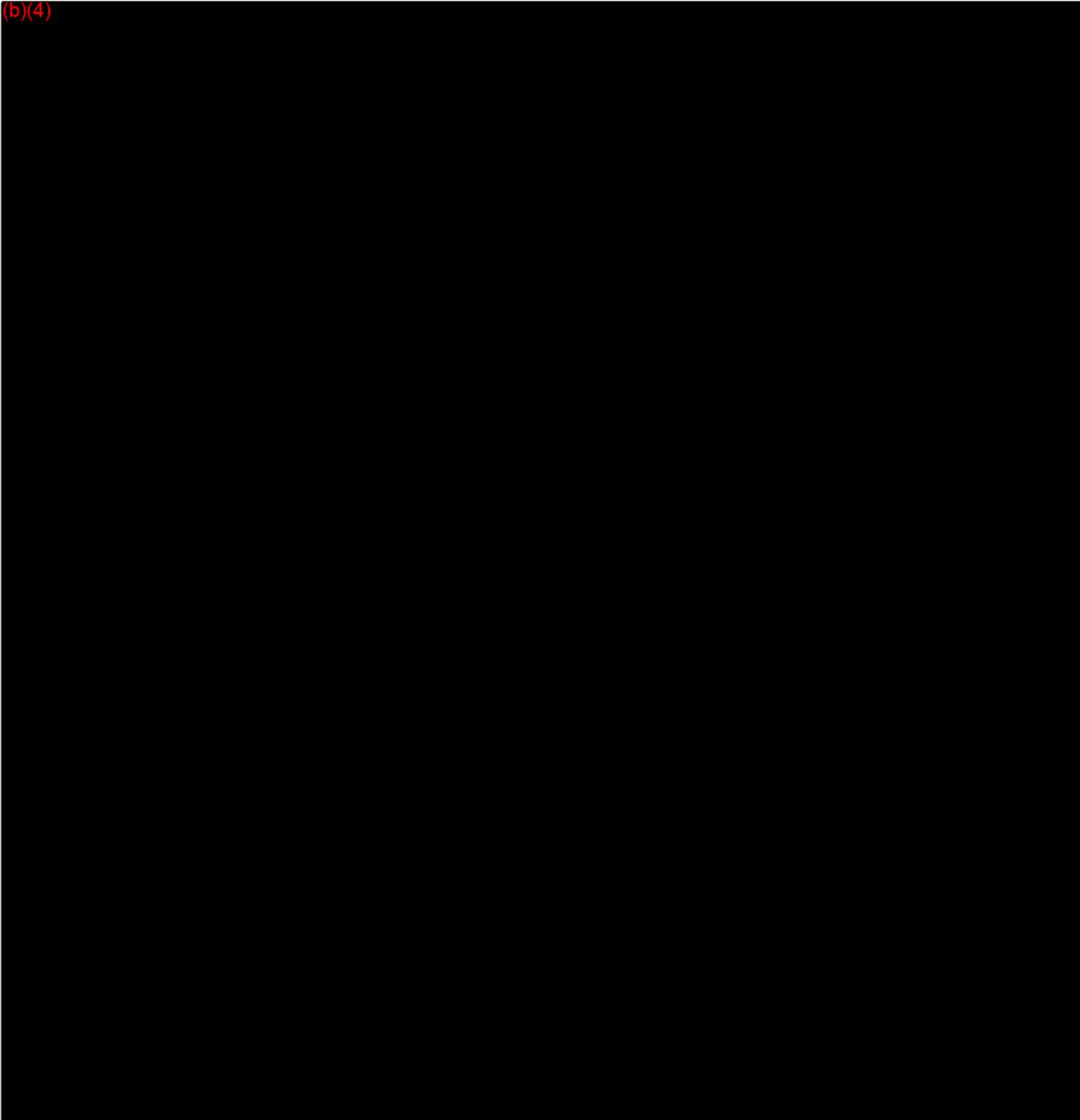
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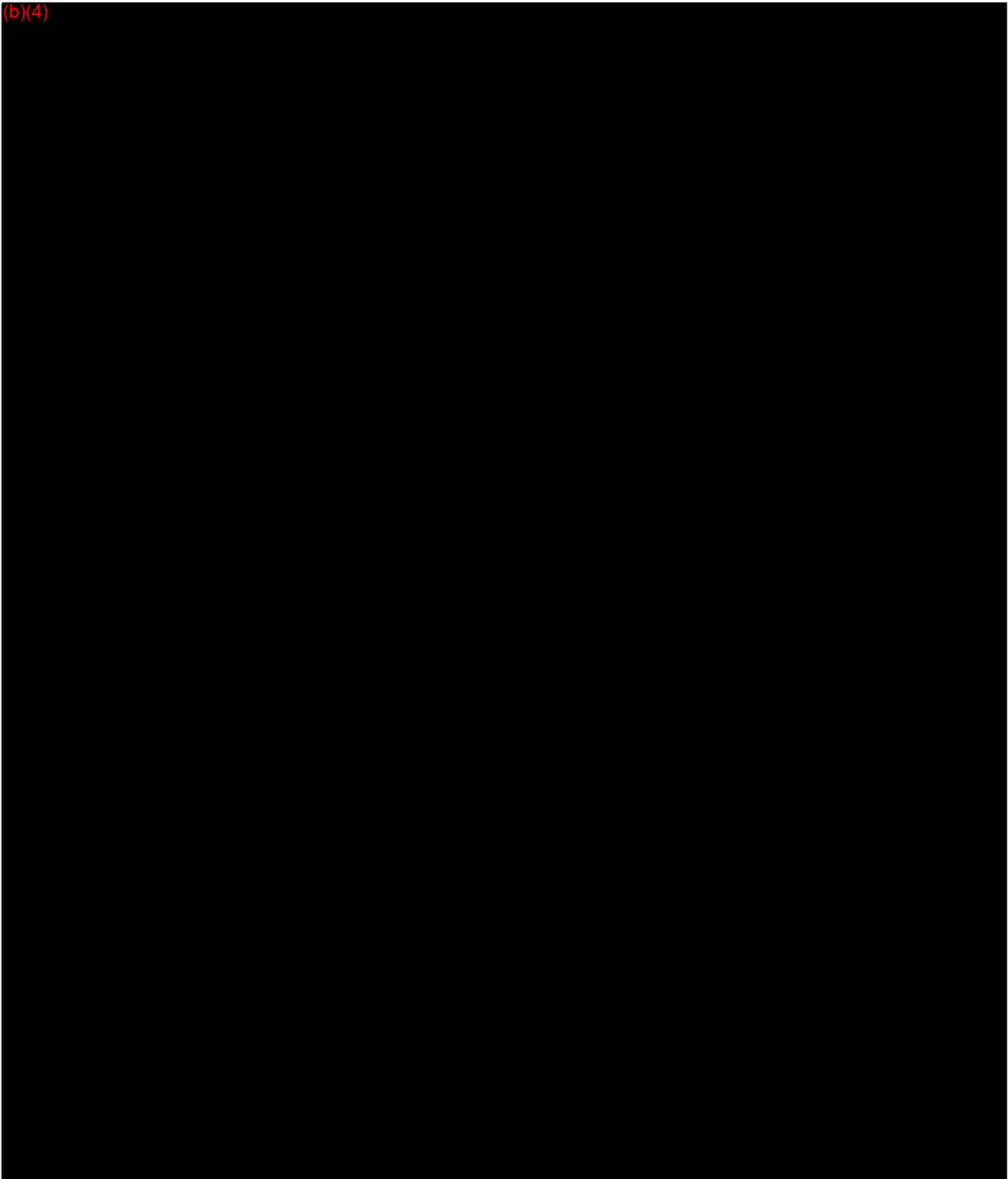
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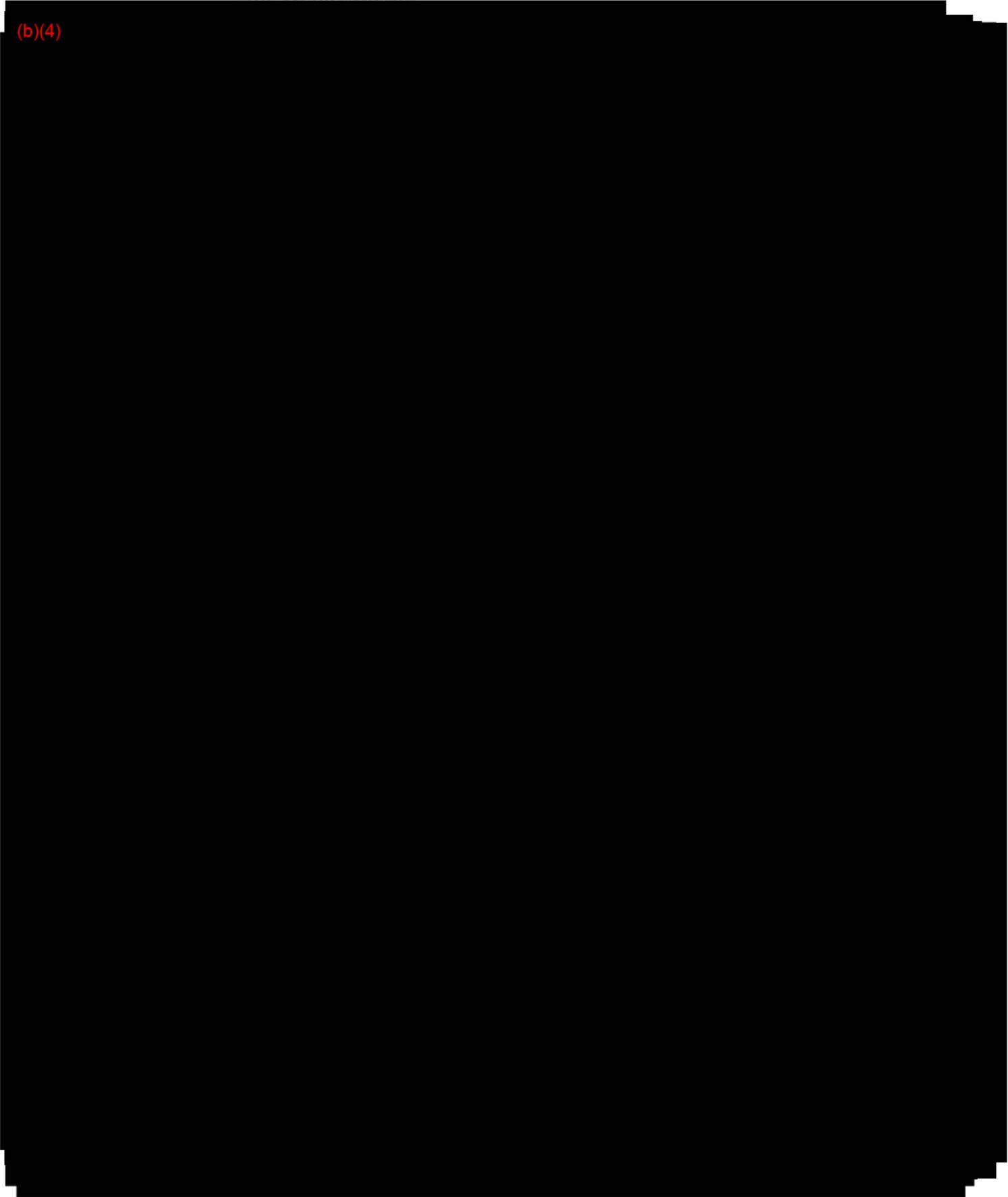
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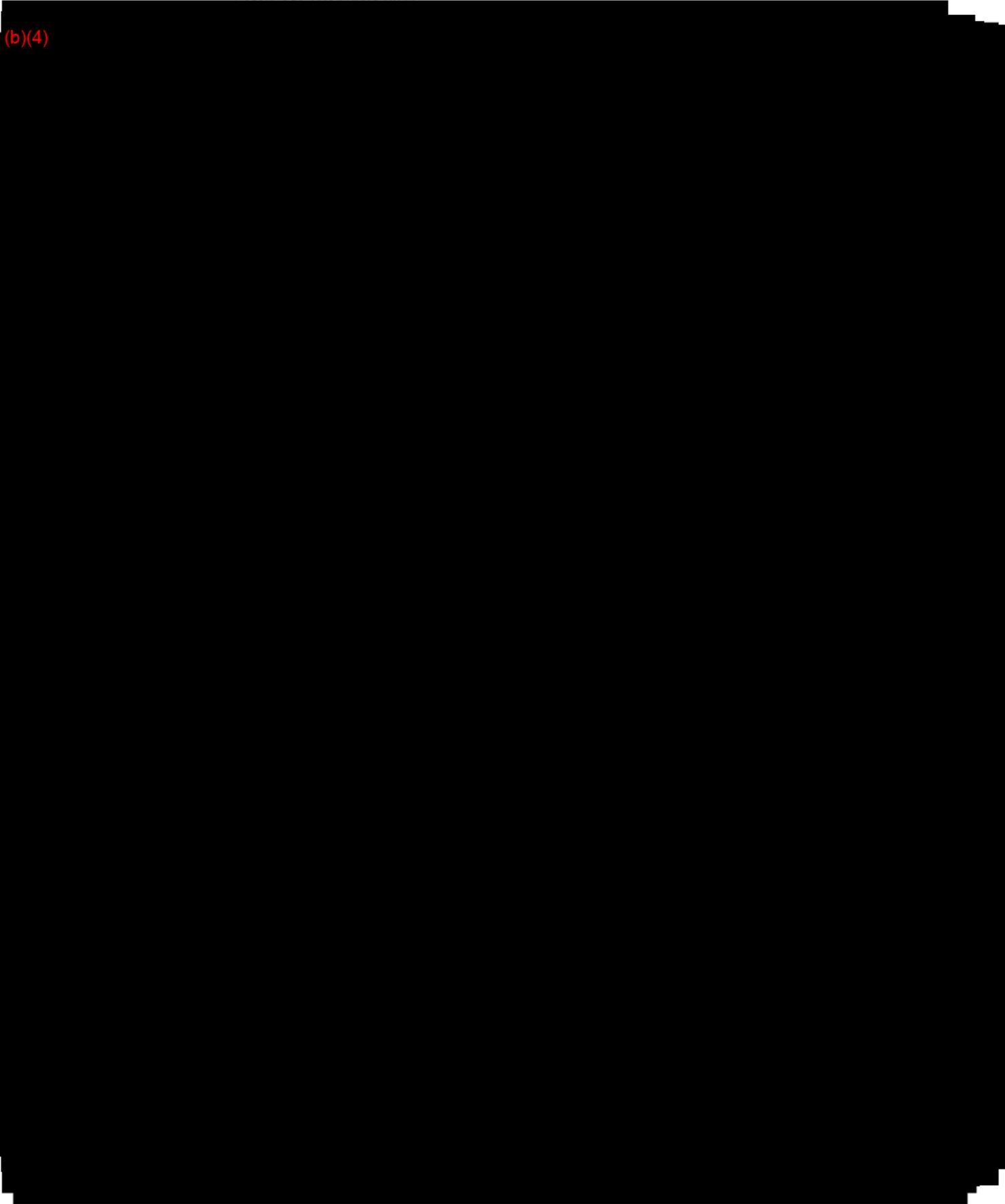
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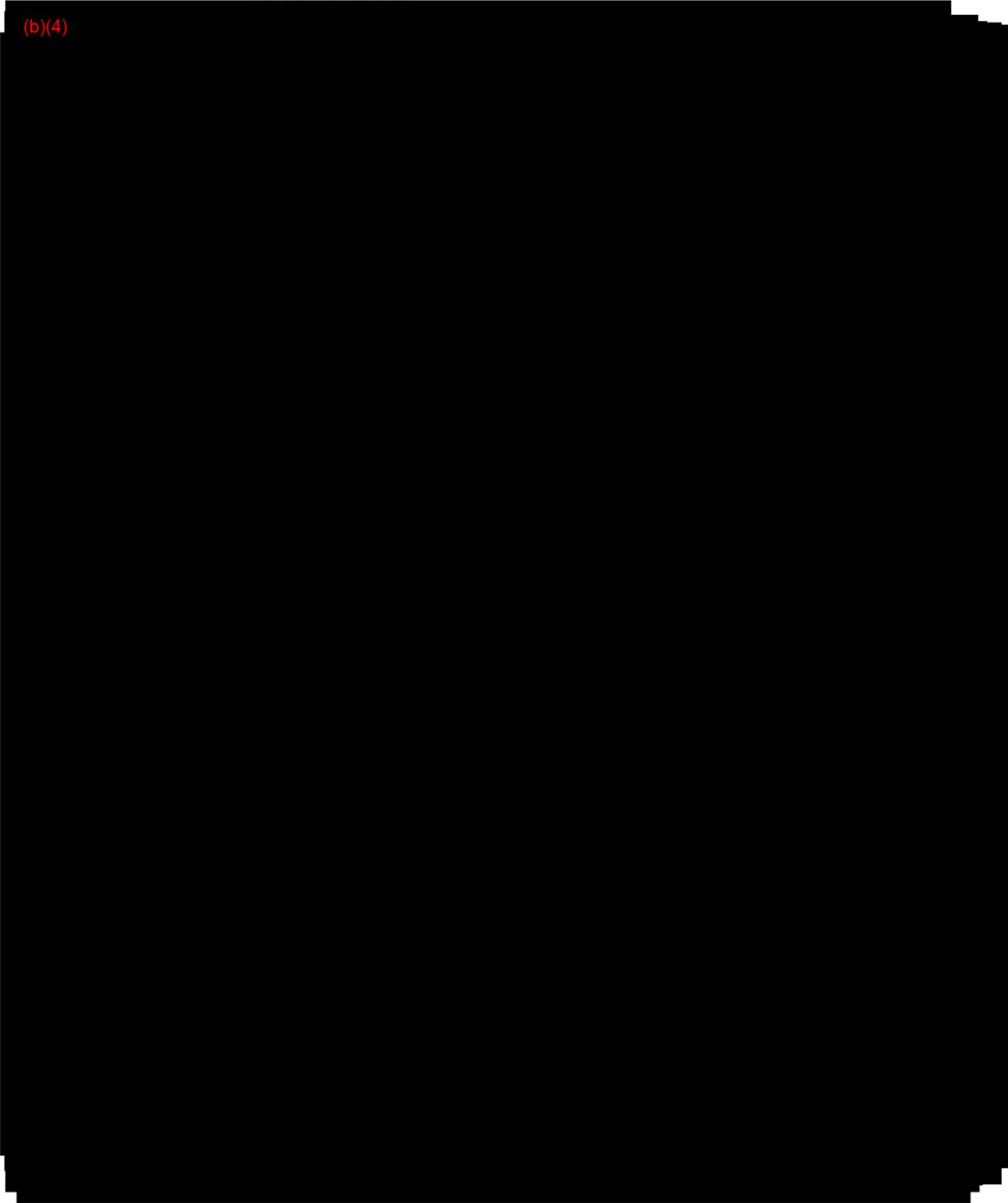
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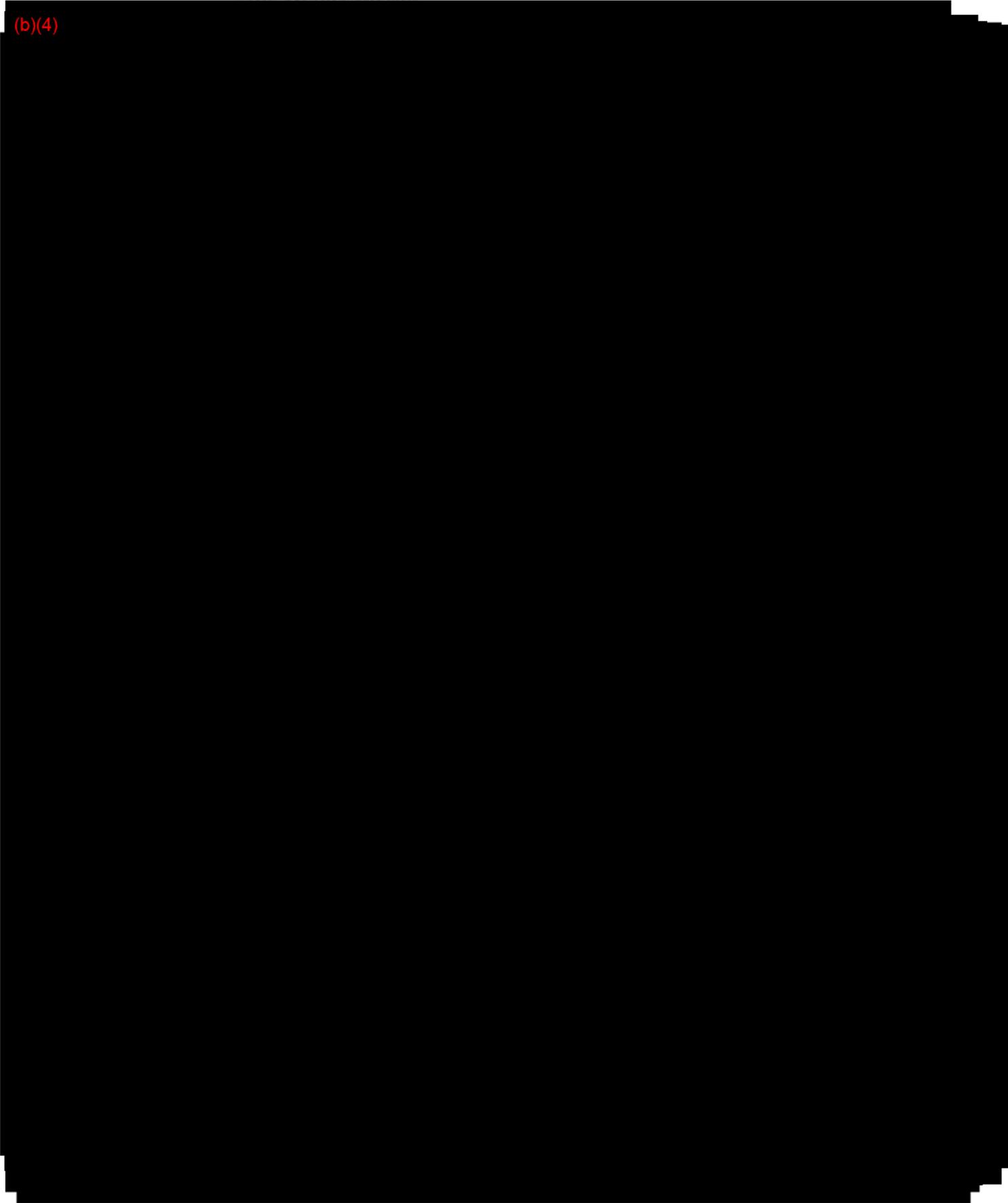
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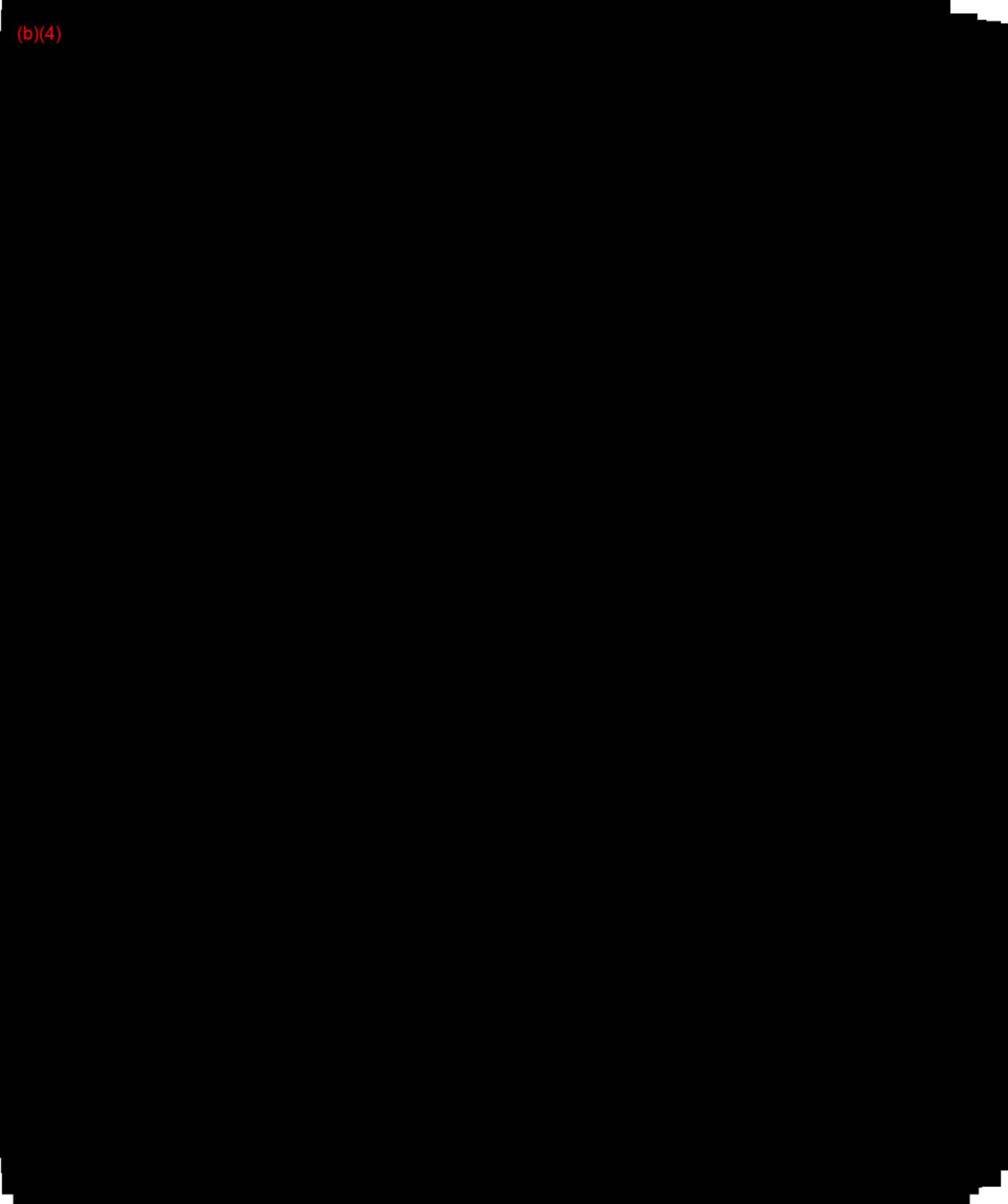
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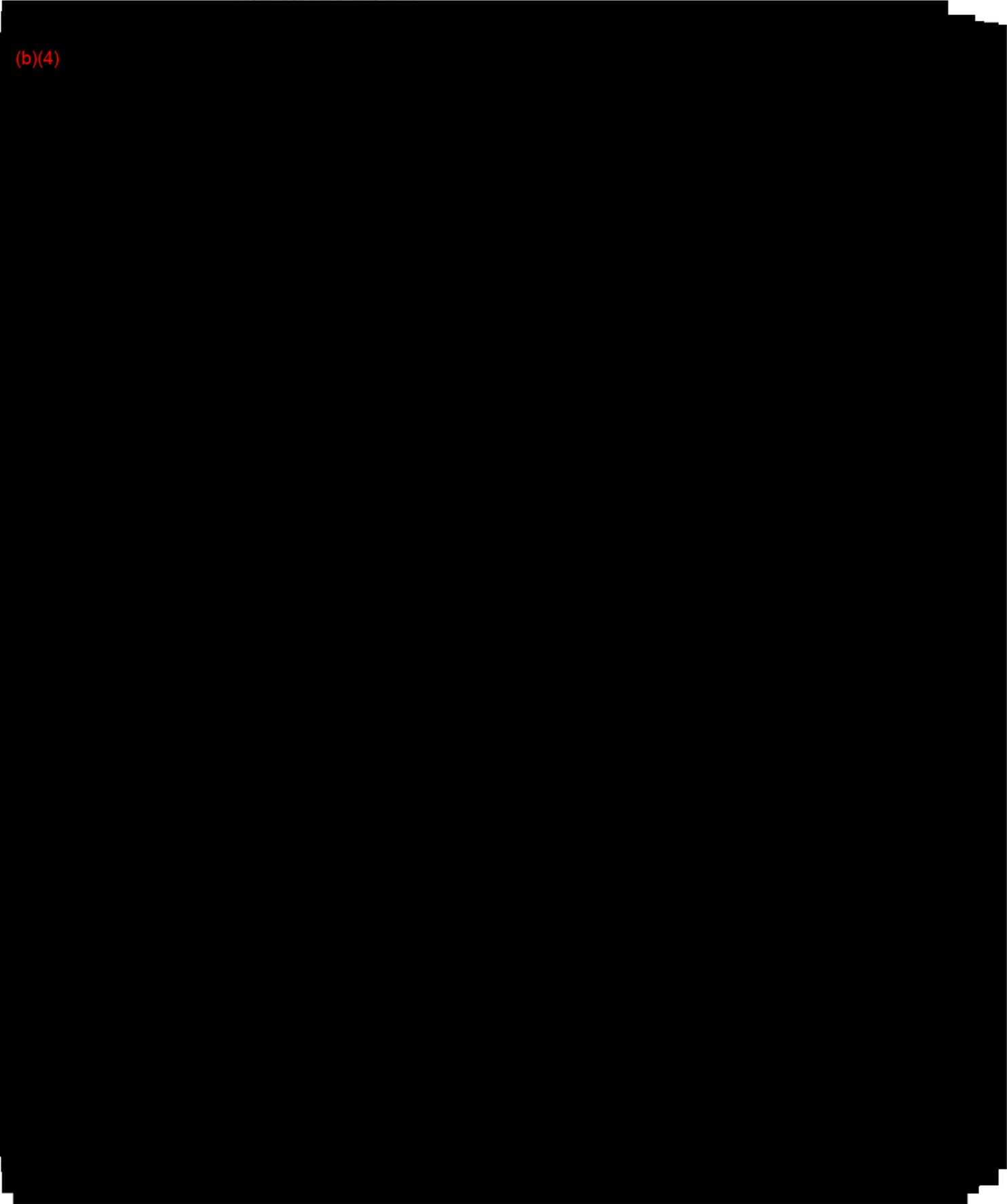
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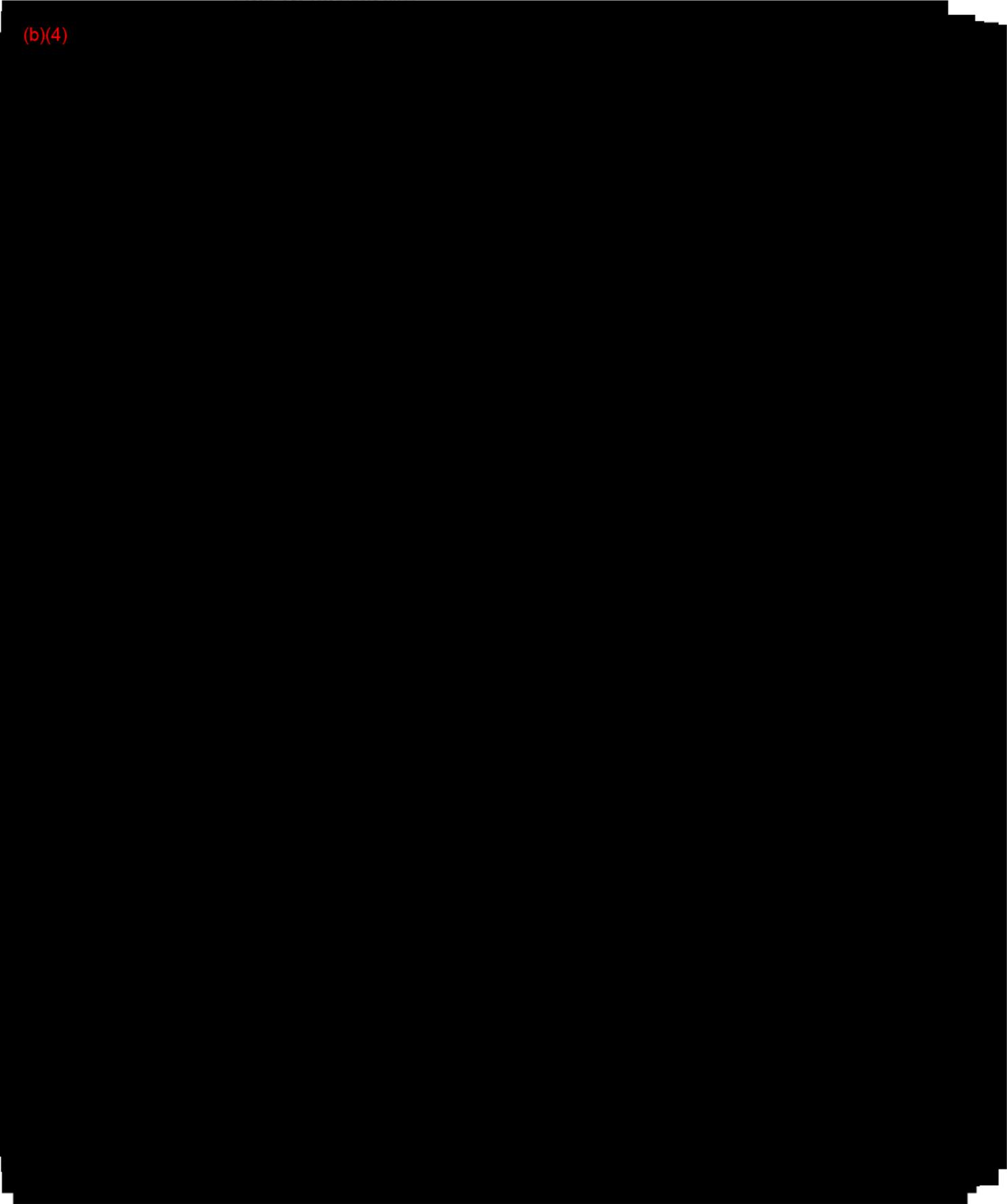
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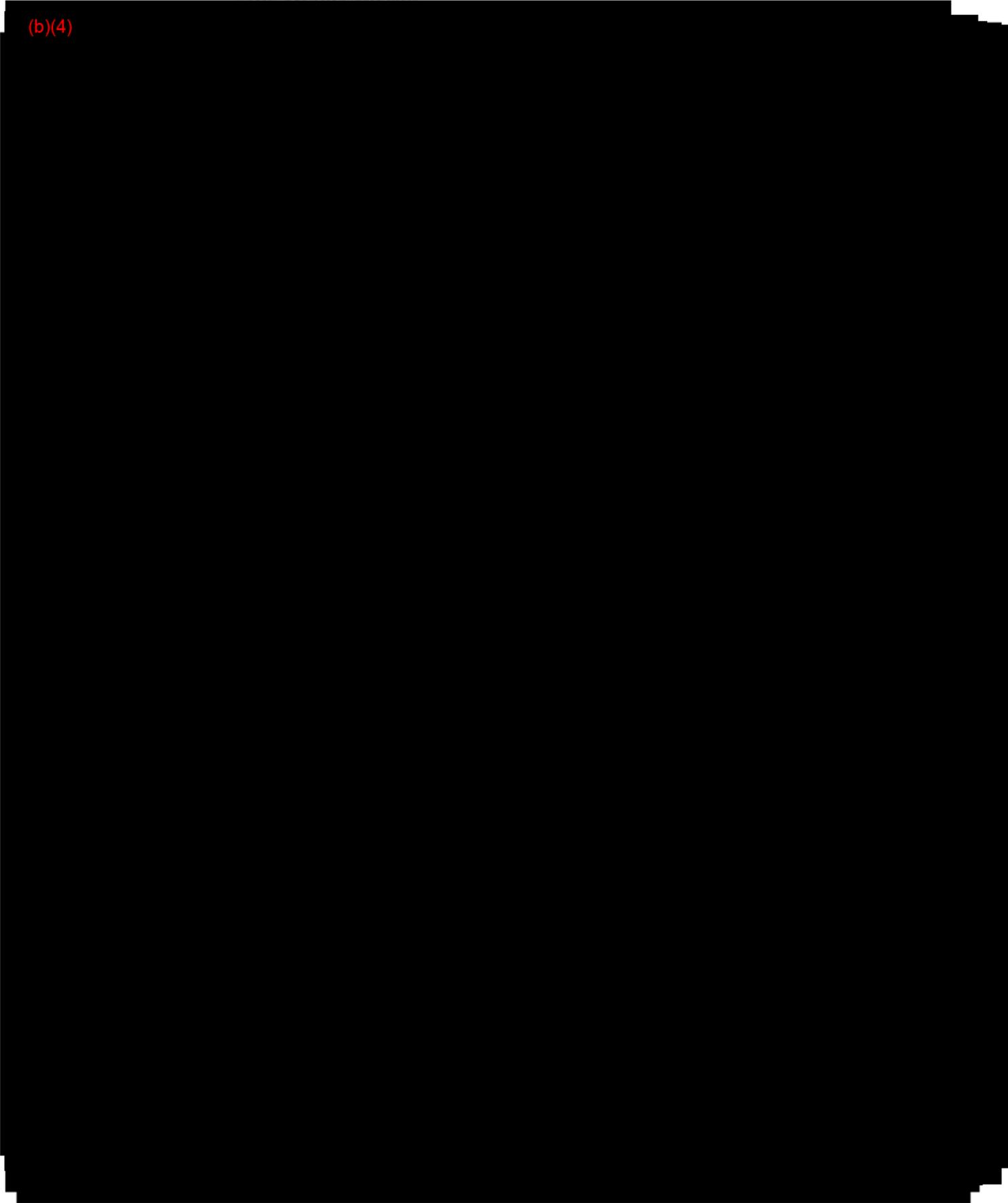
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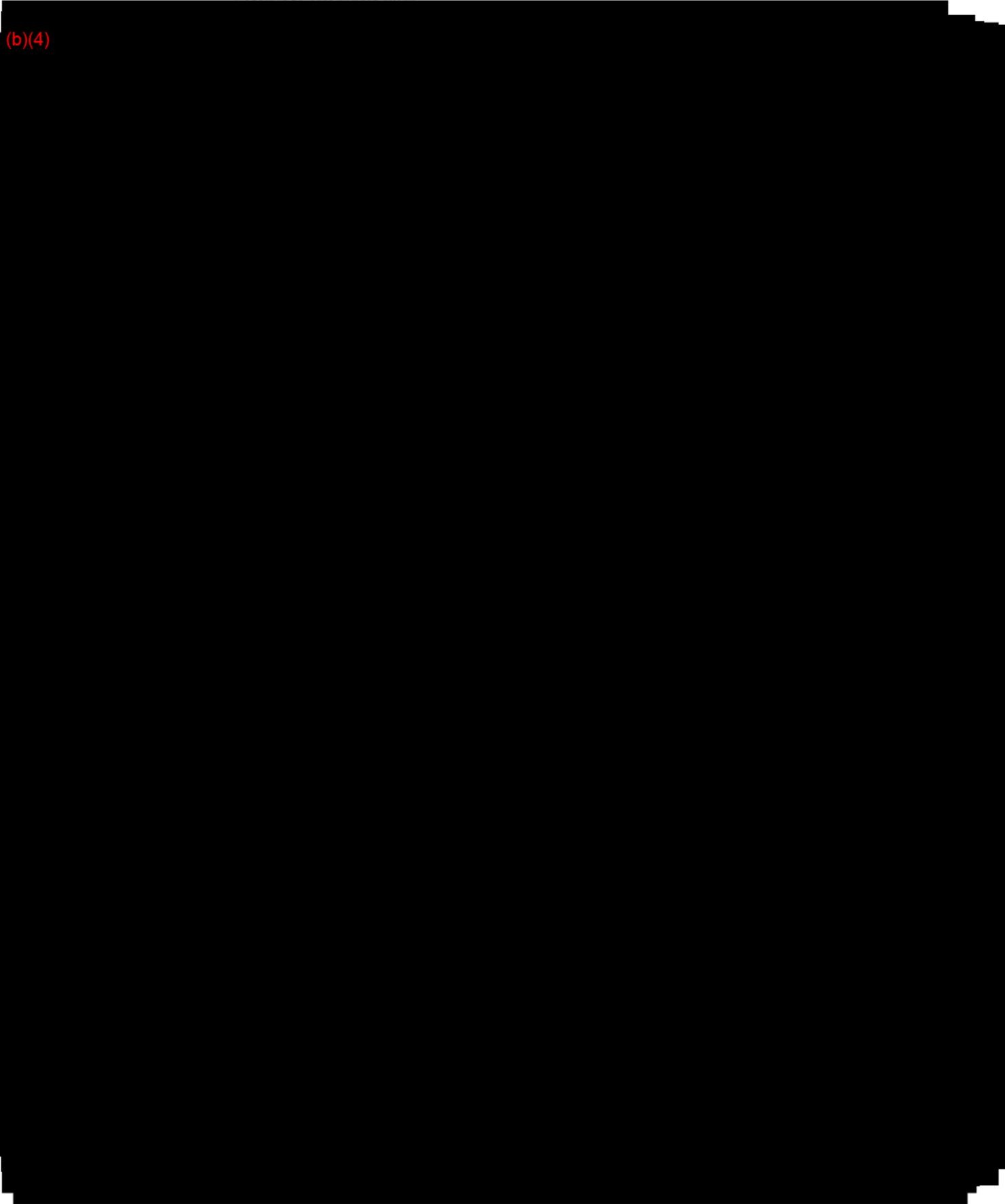
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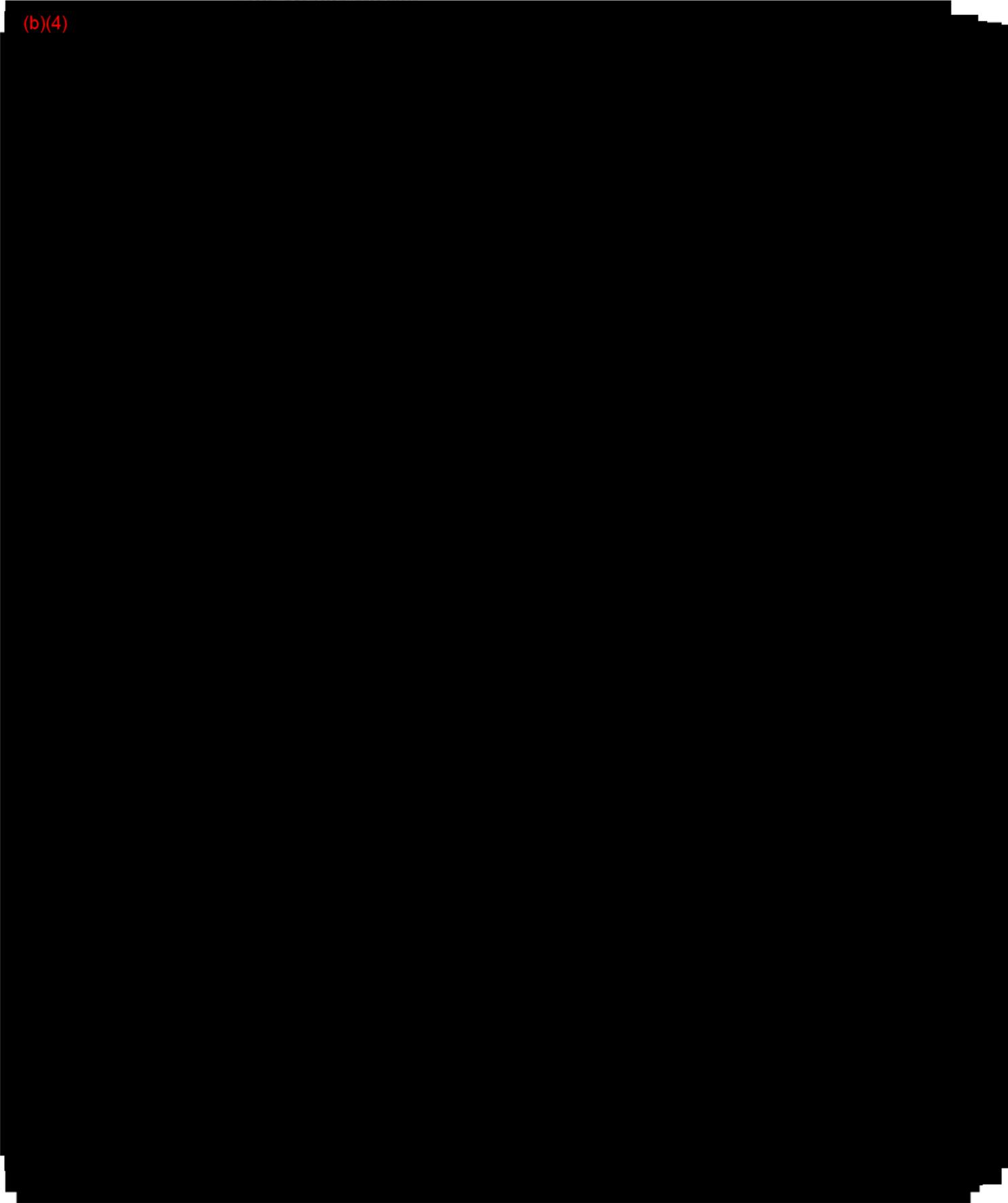
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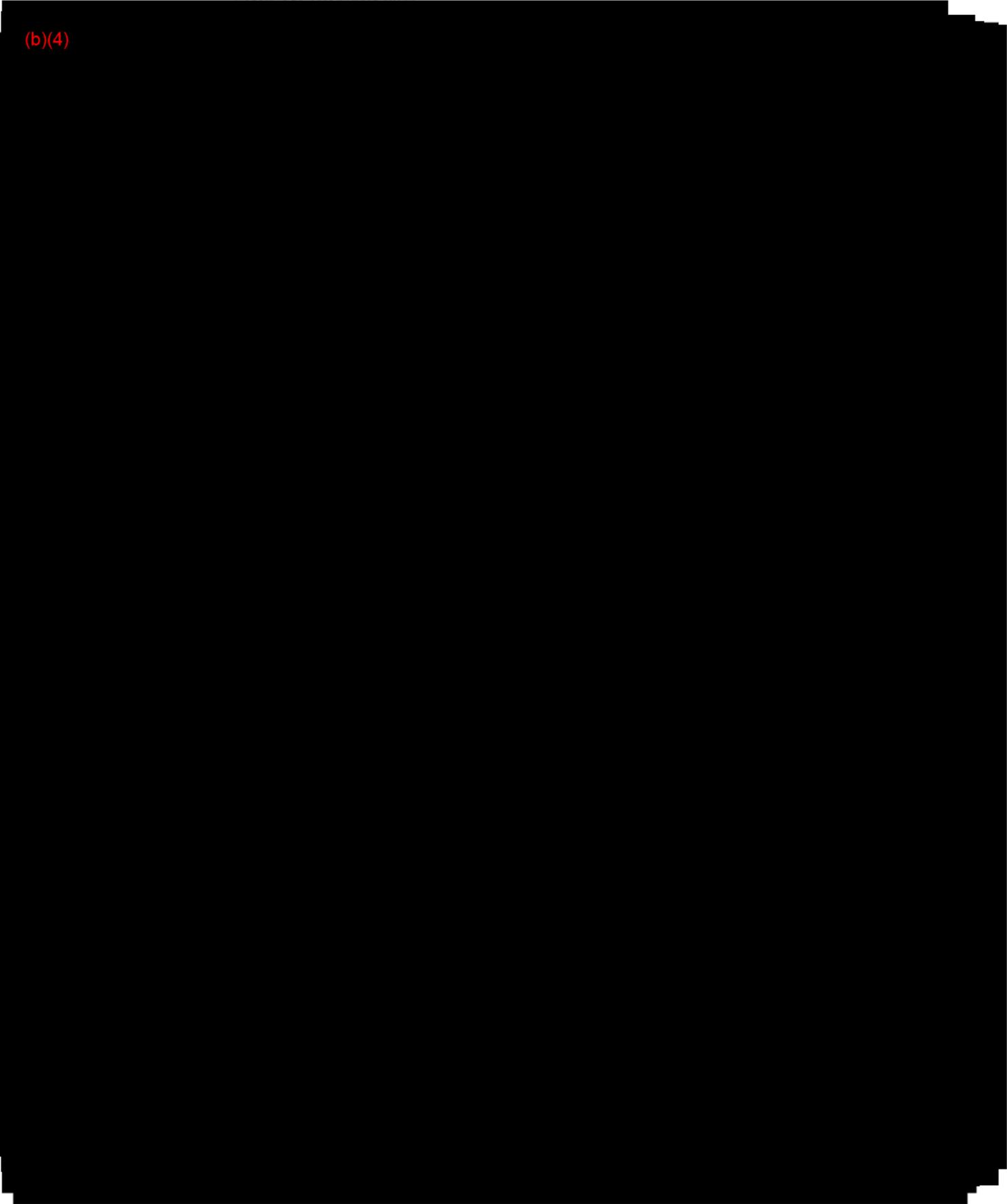
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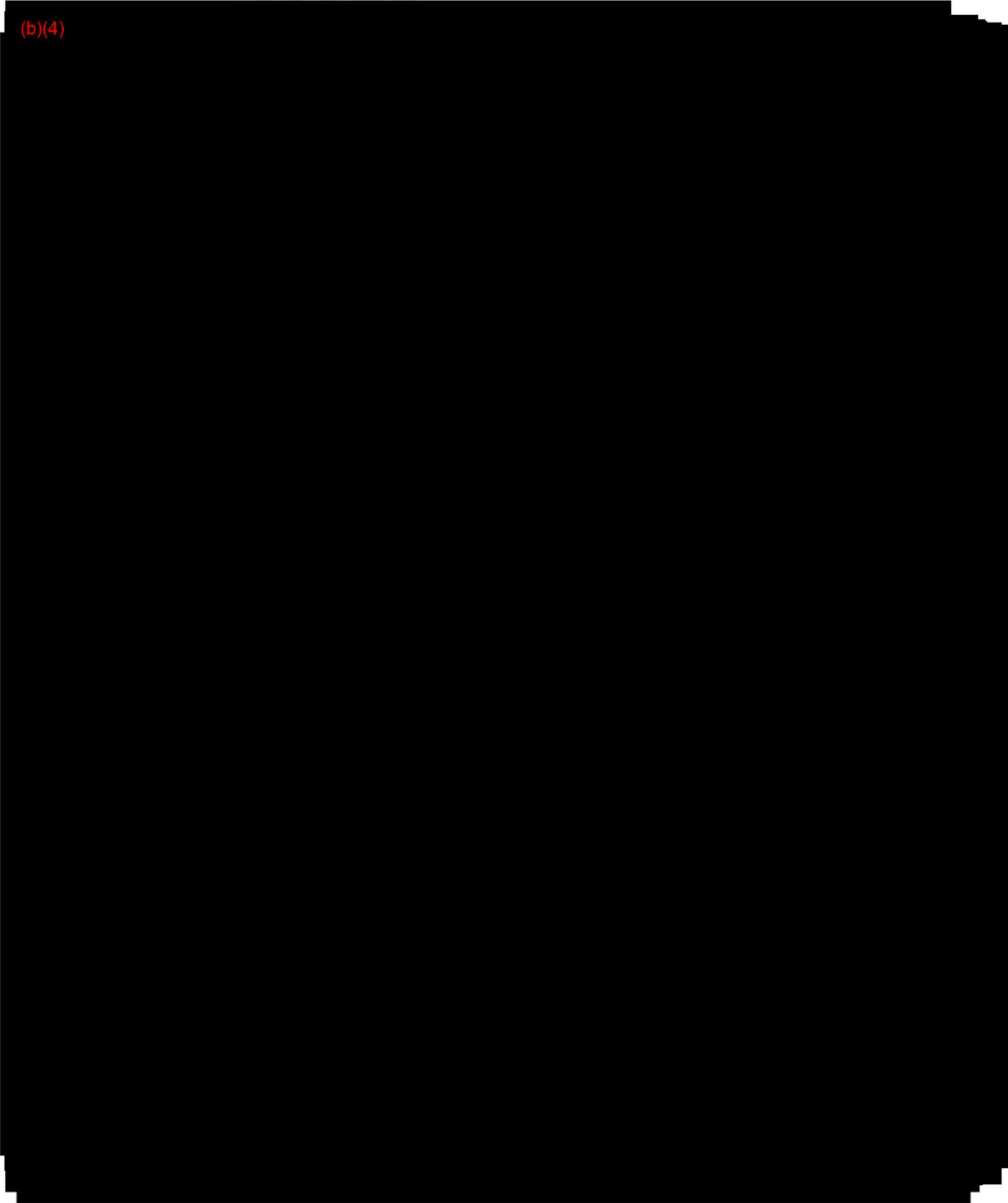
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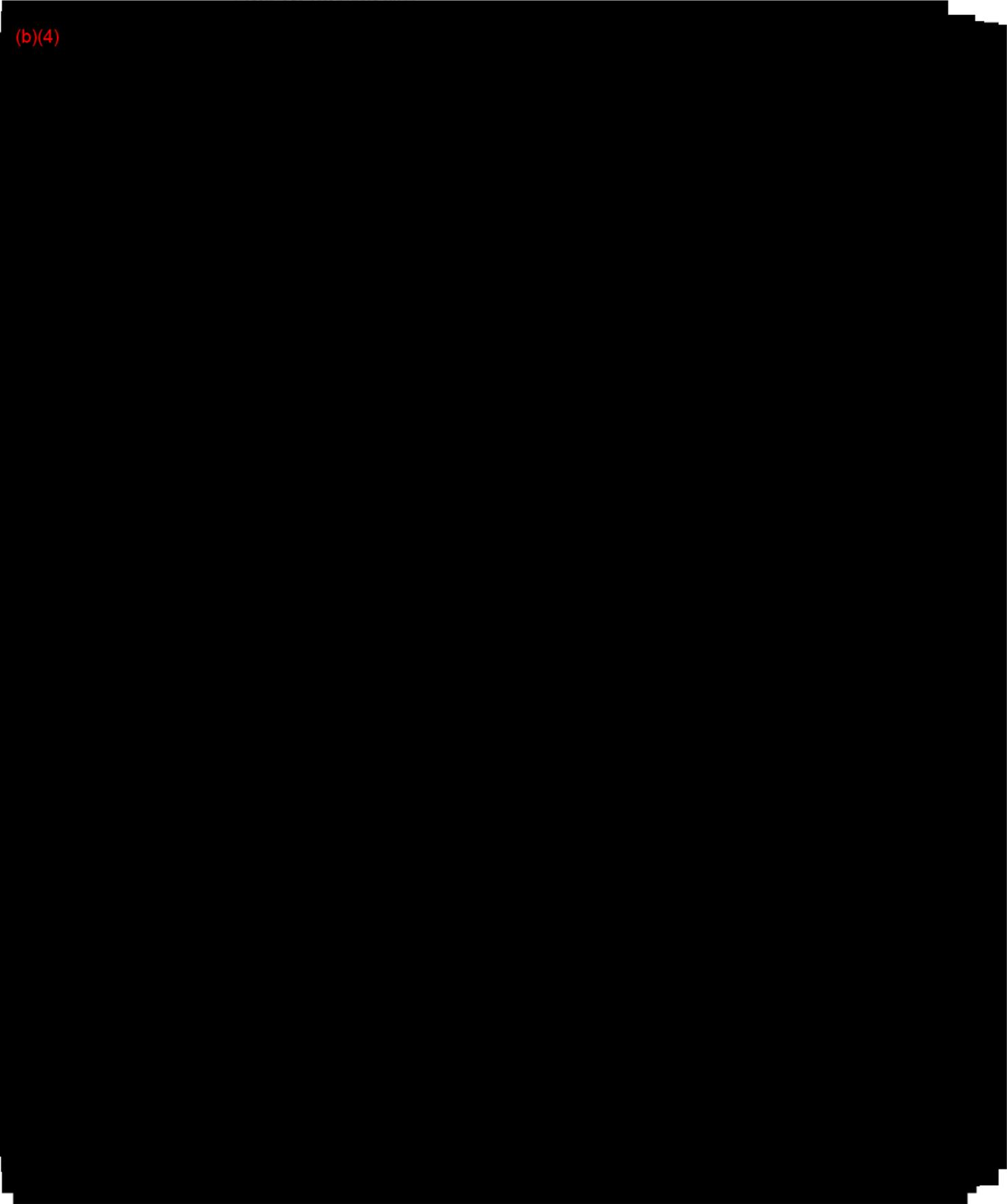
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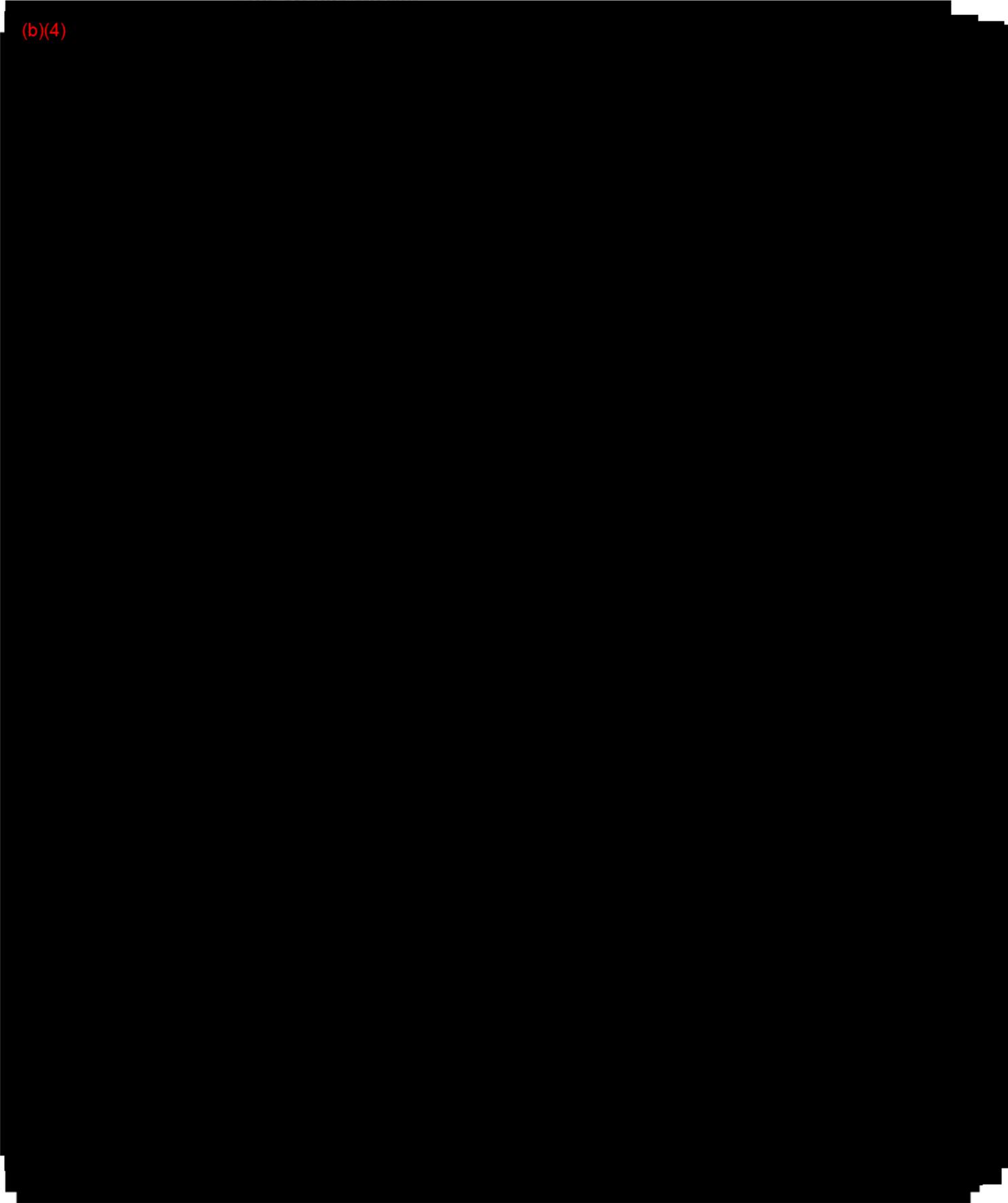
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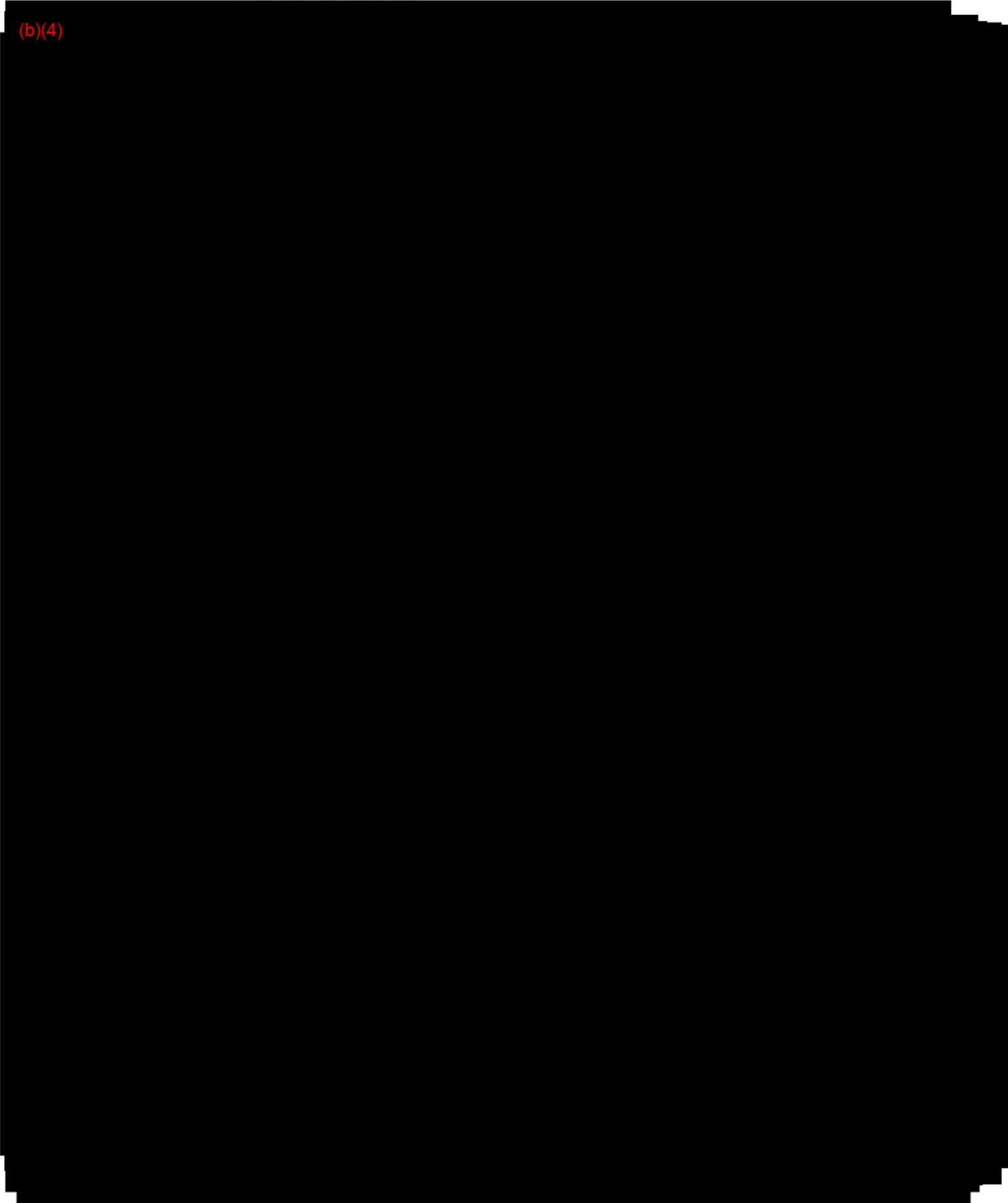
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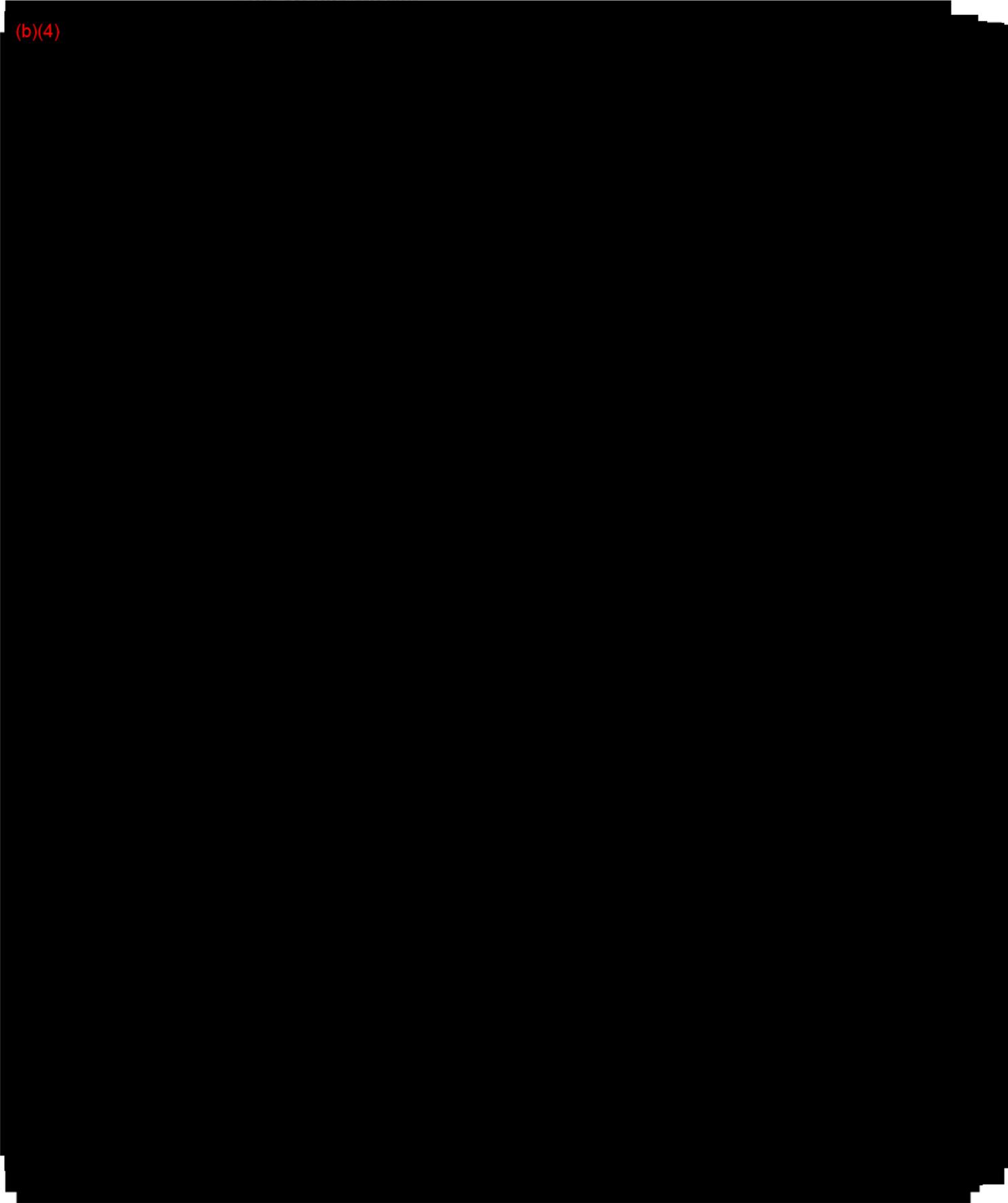
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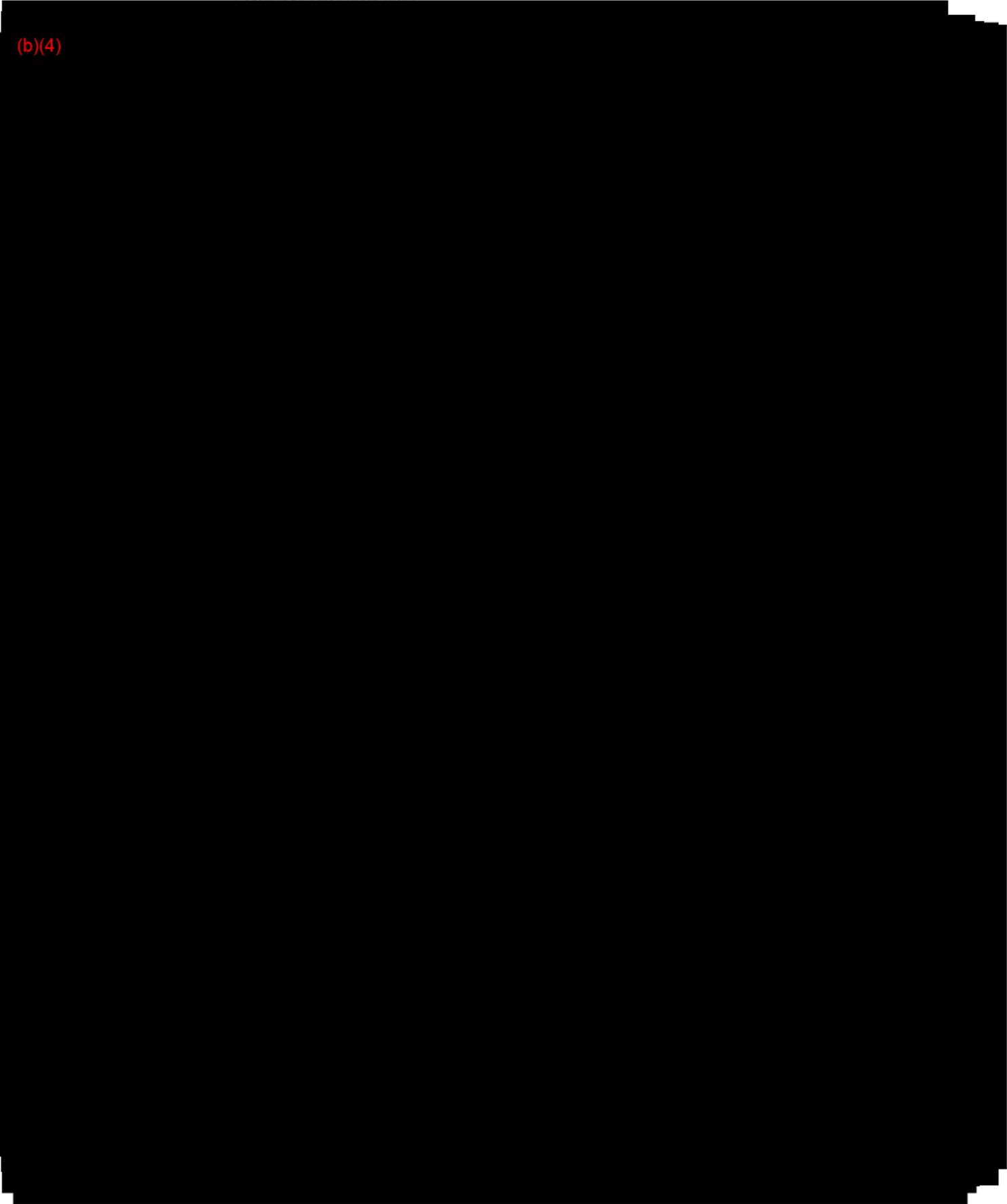
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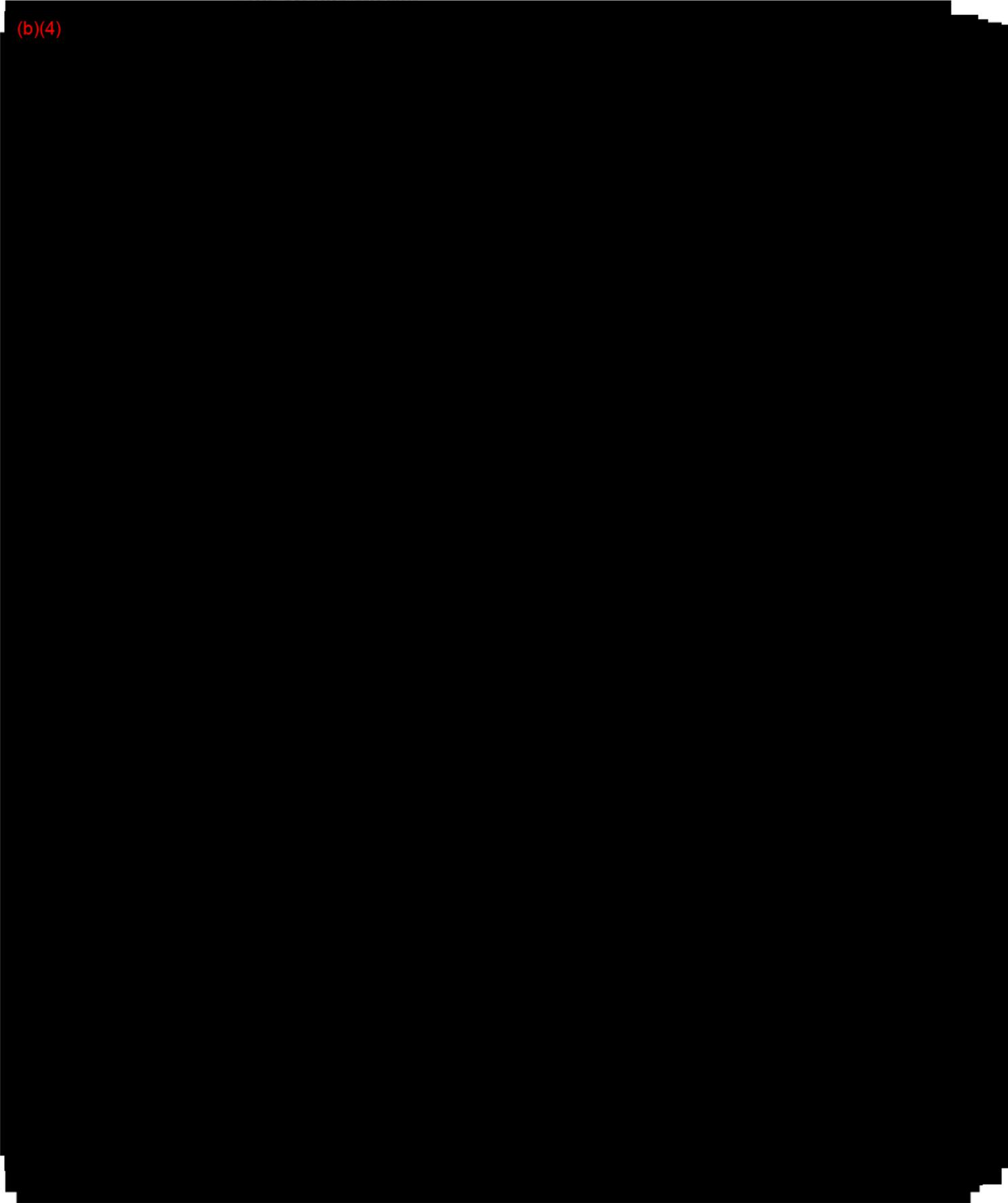
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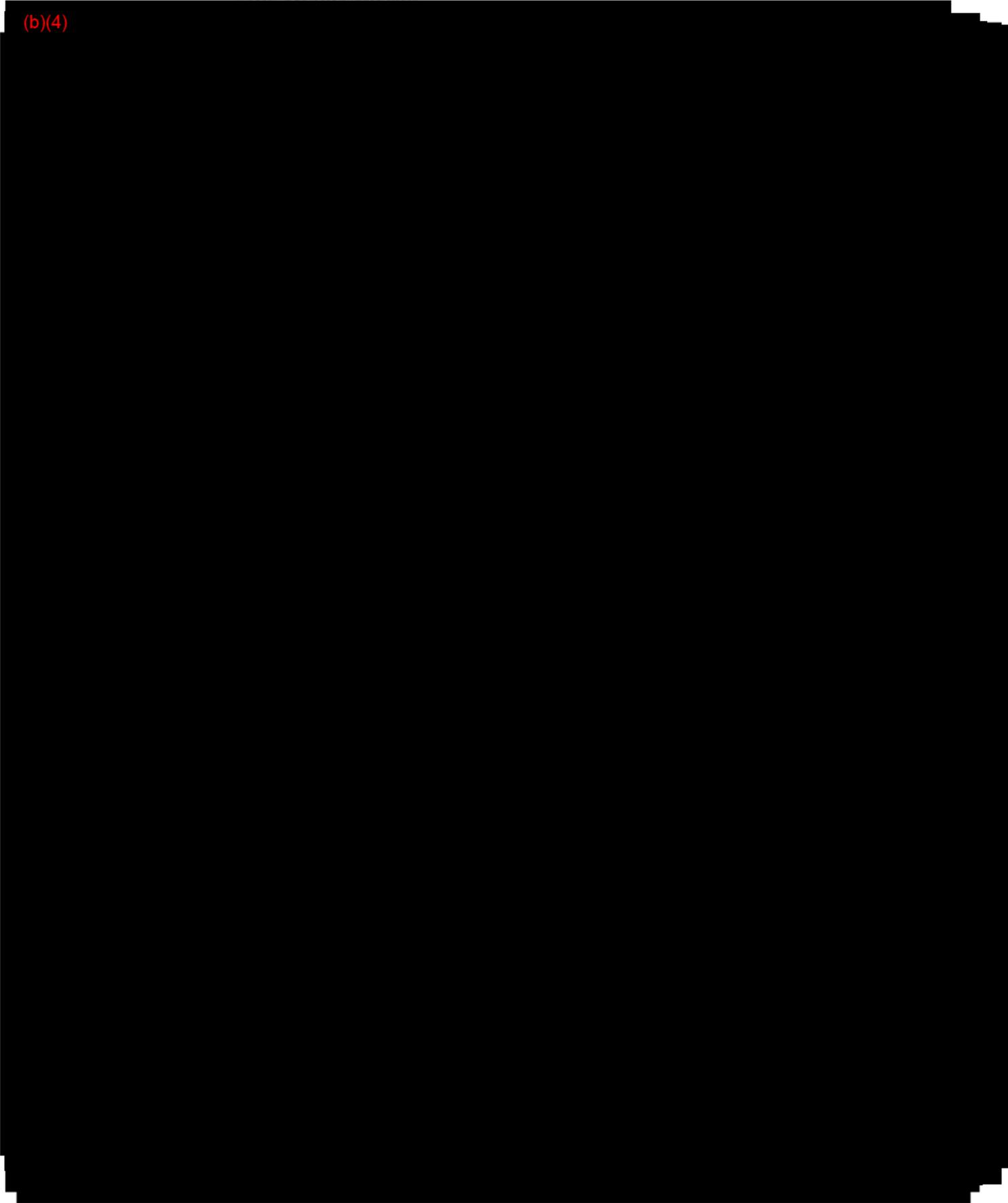
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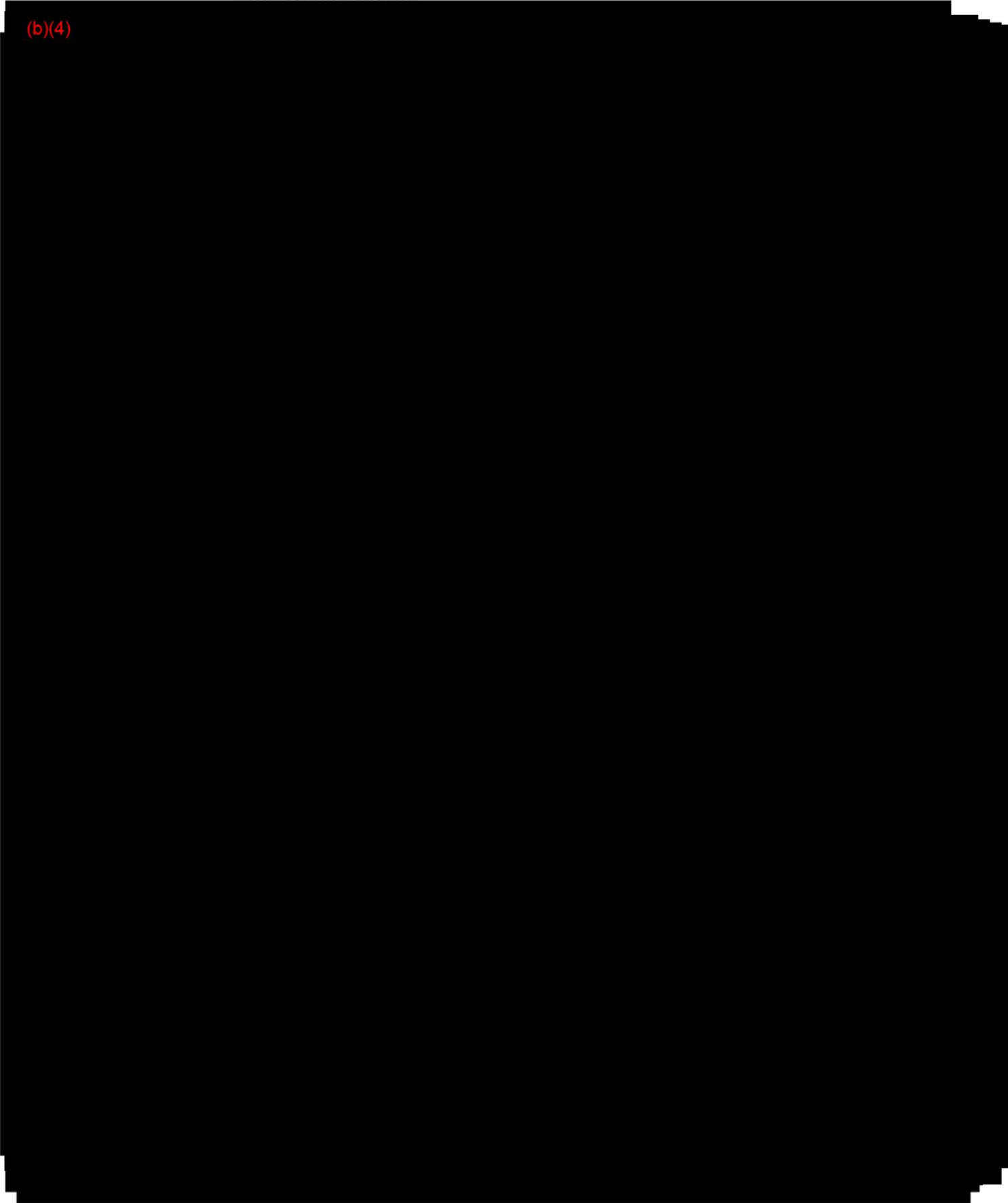
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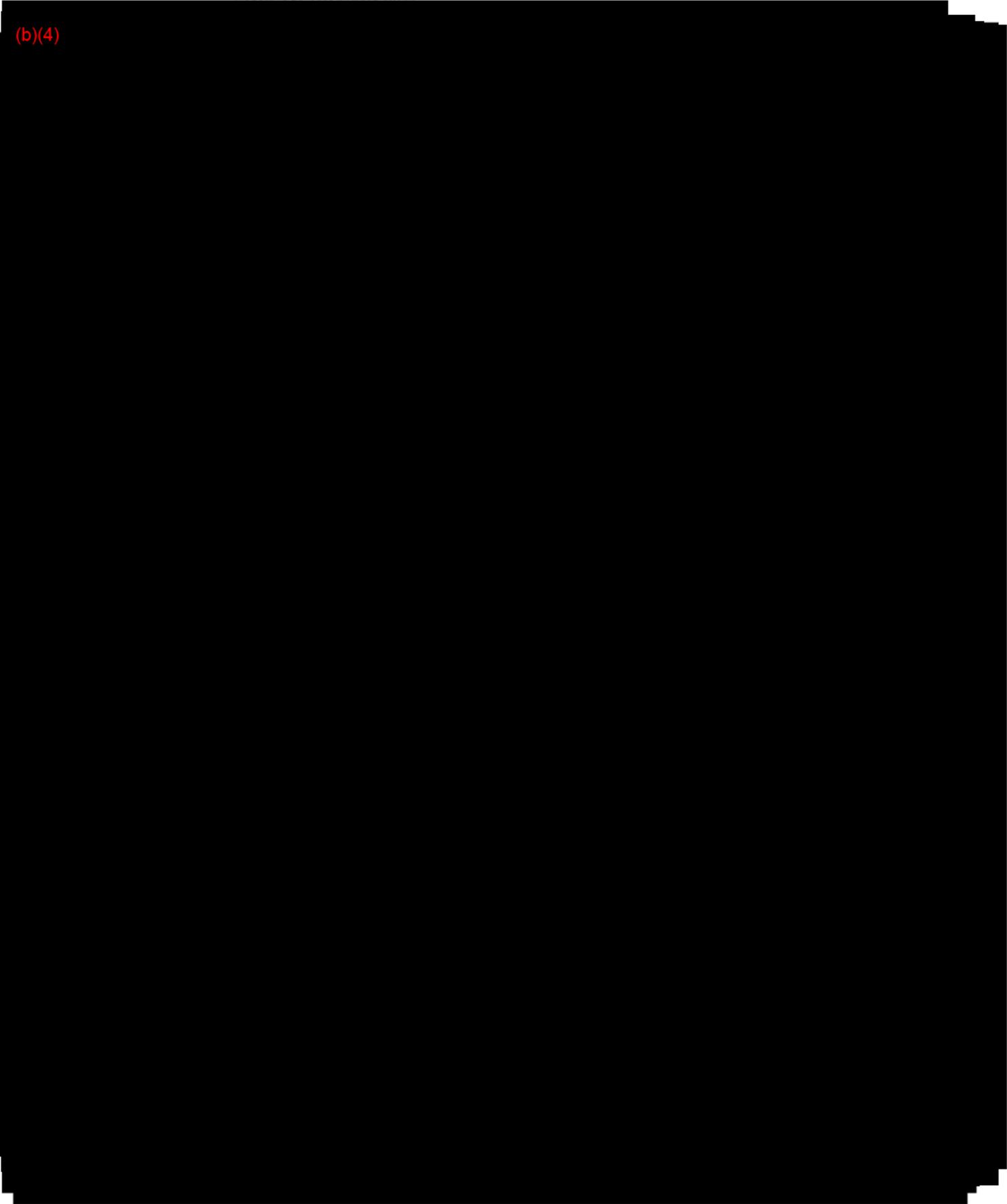
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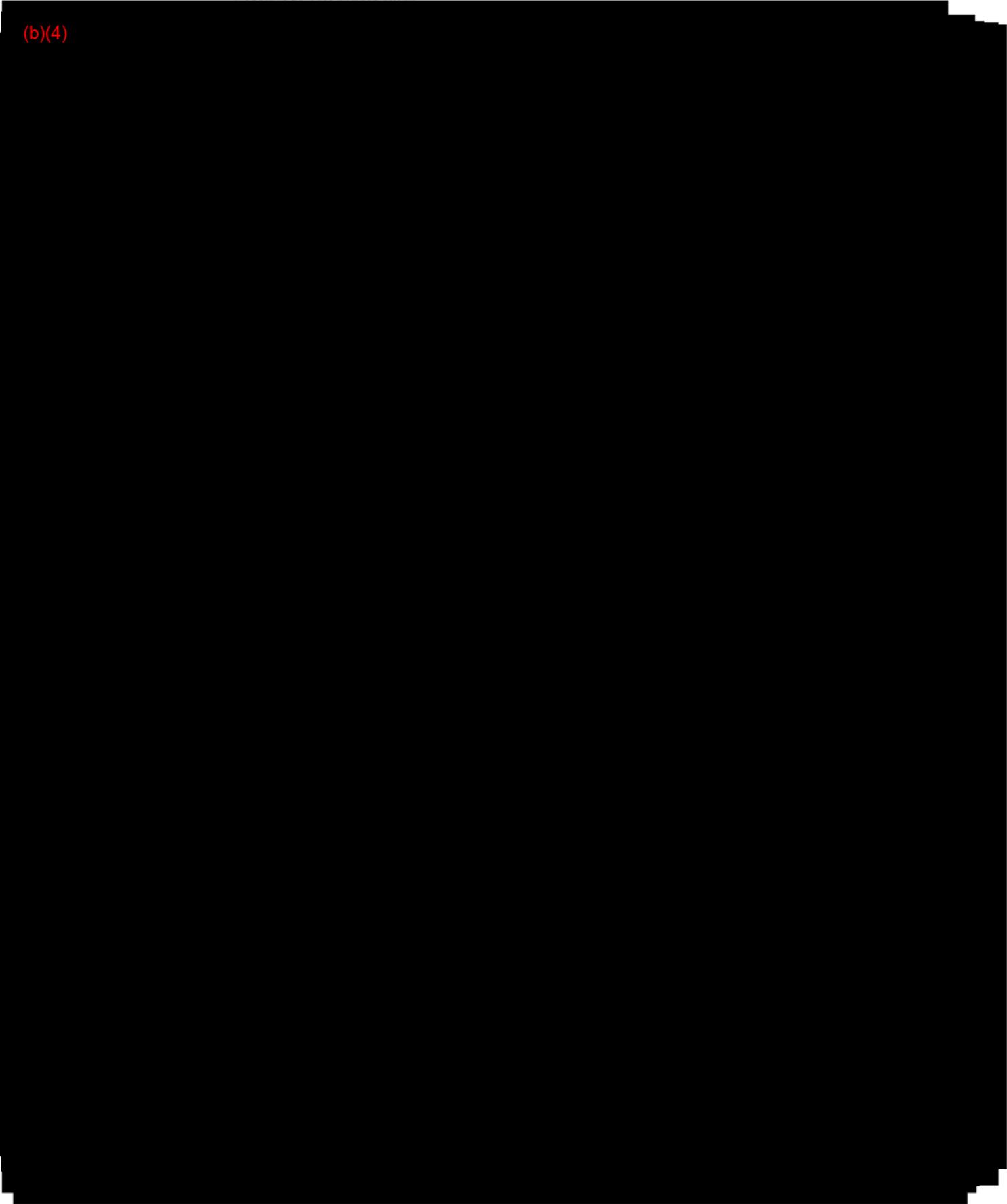
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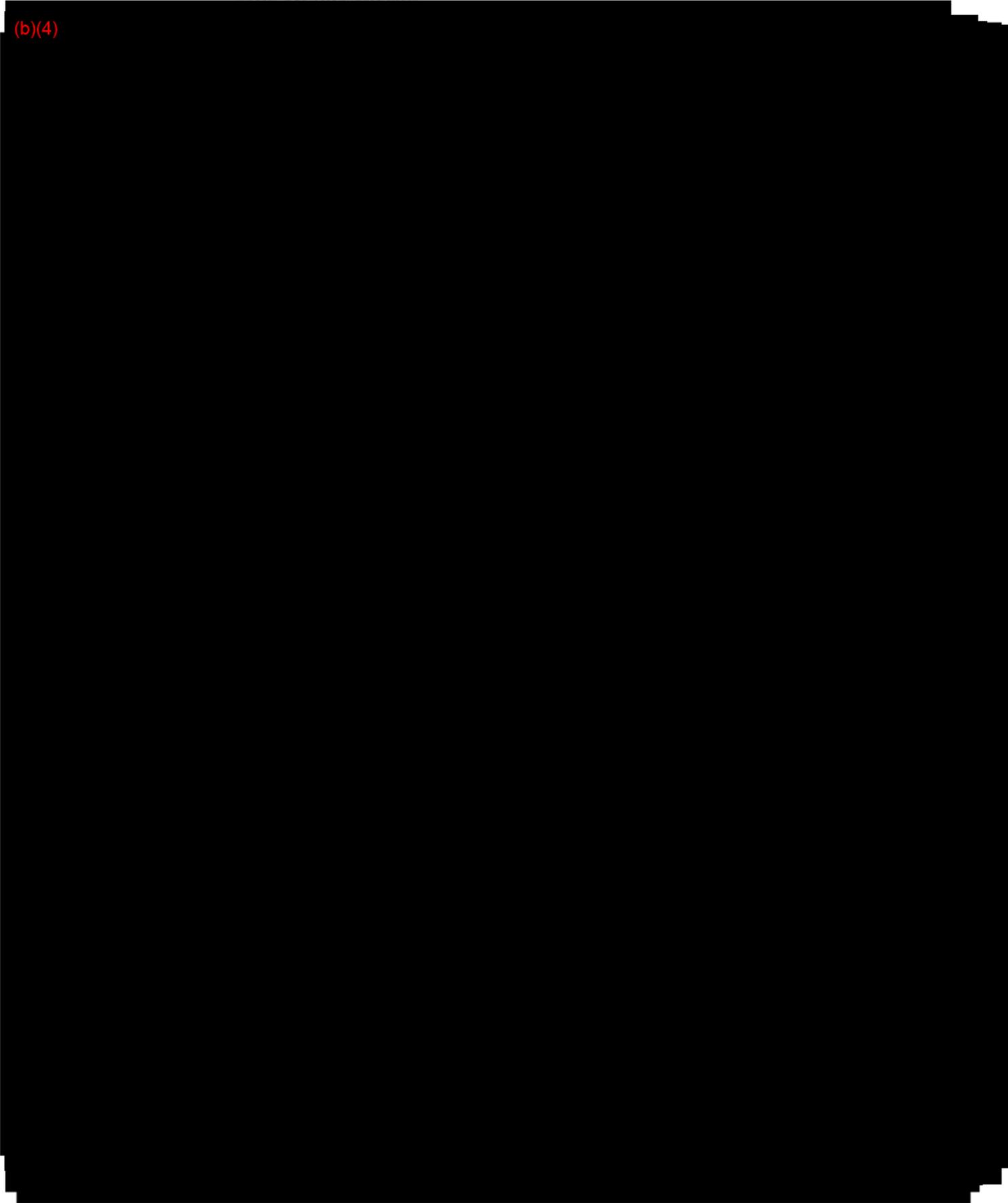
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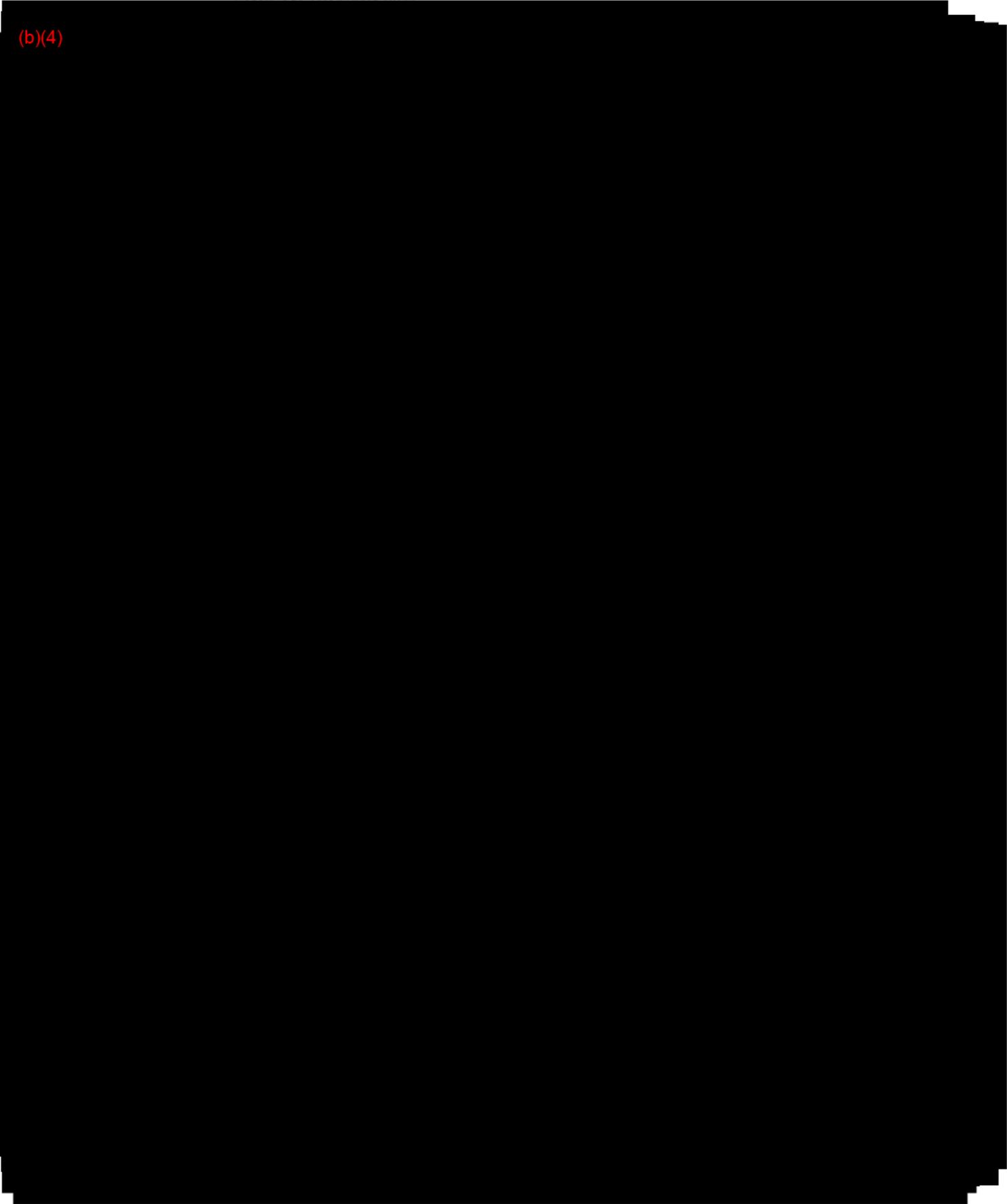
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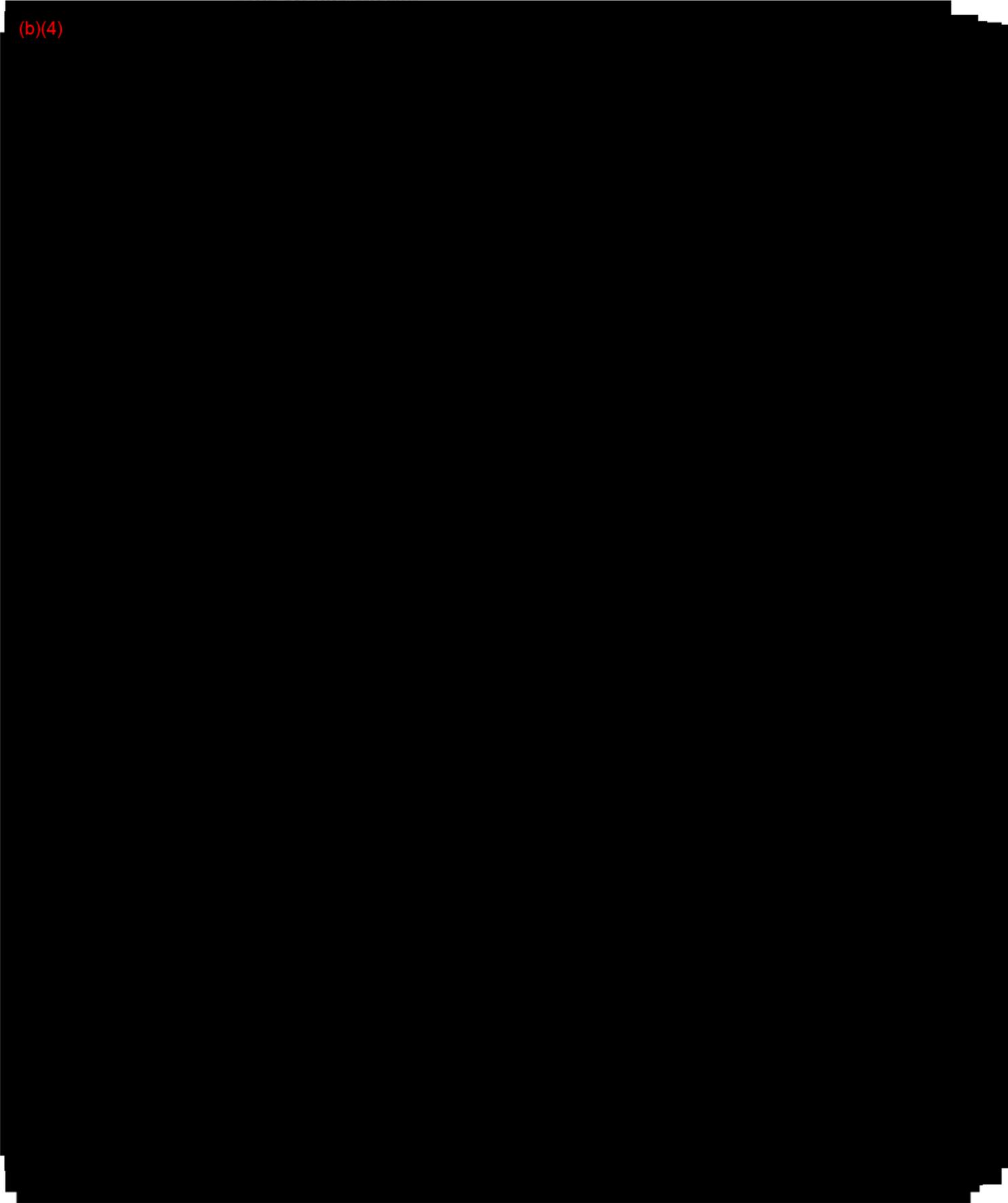
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Confidential Proprietary Information

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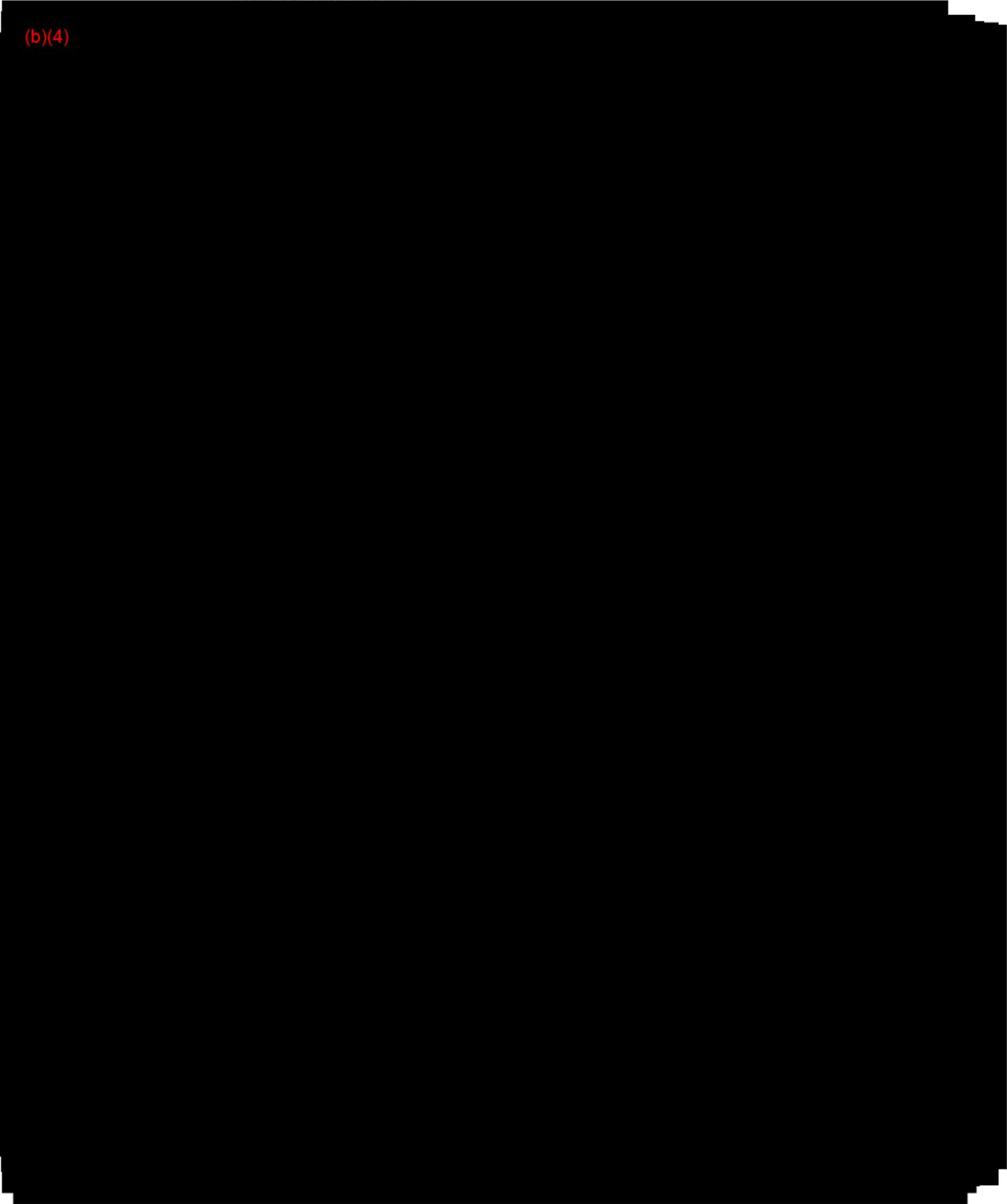
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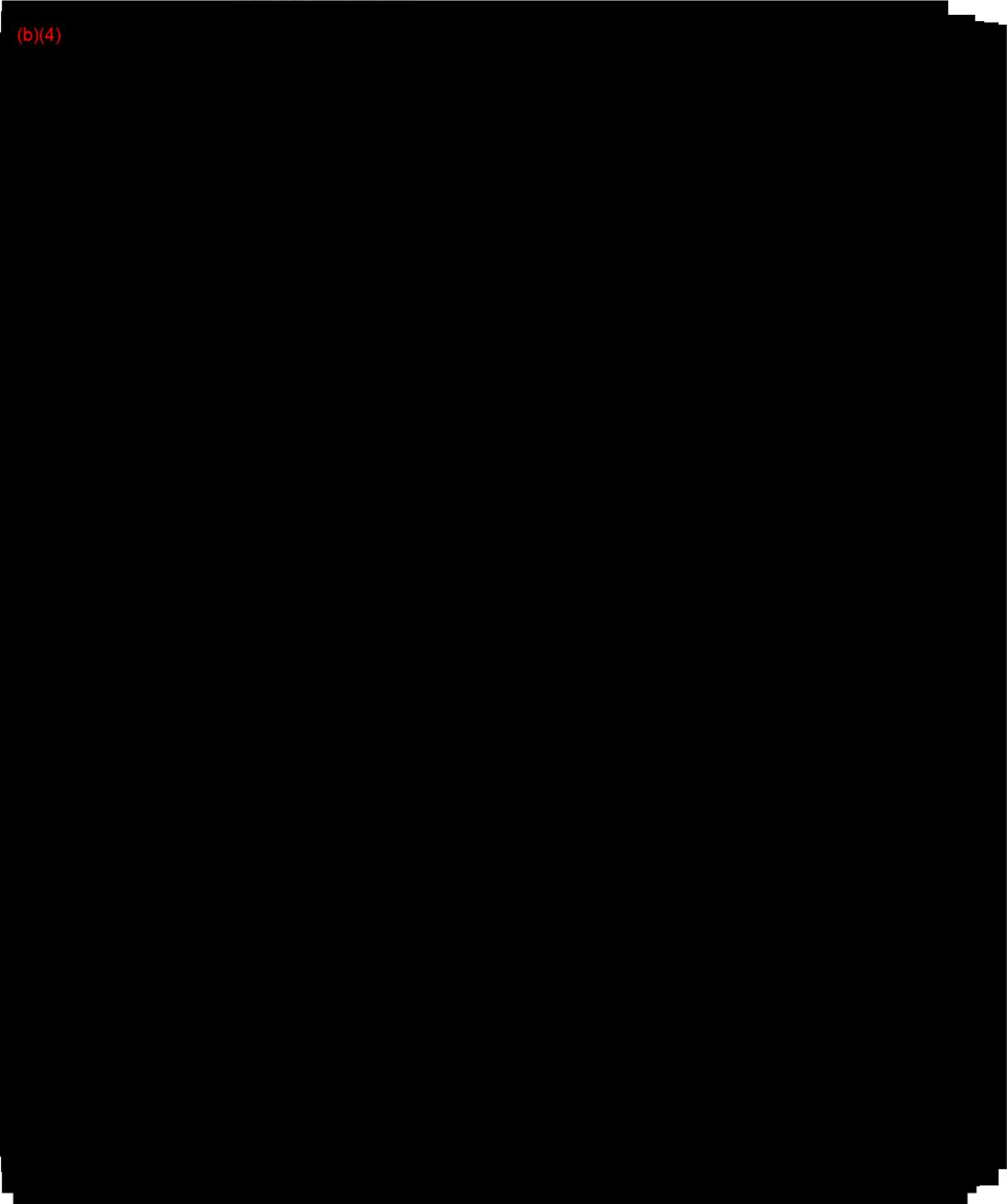
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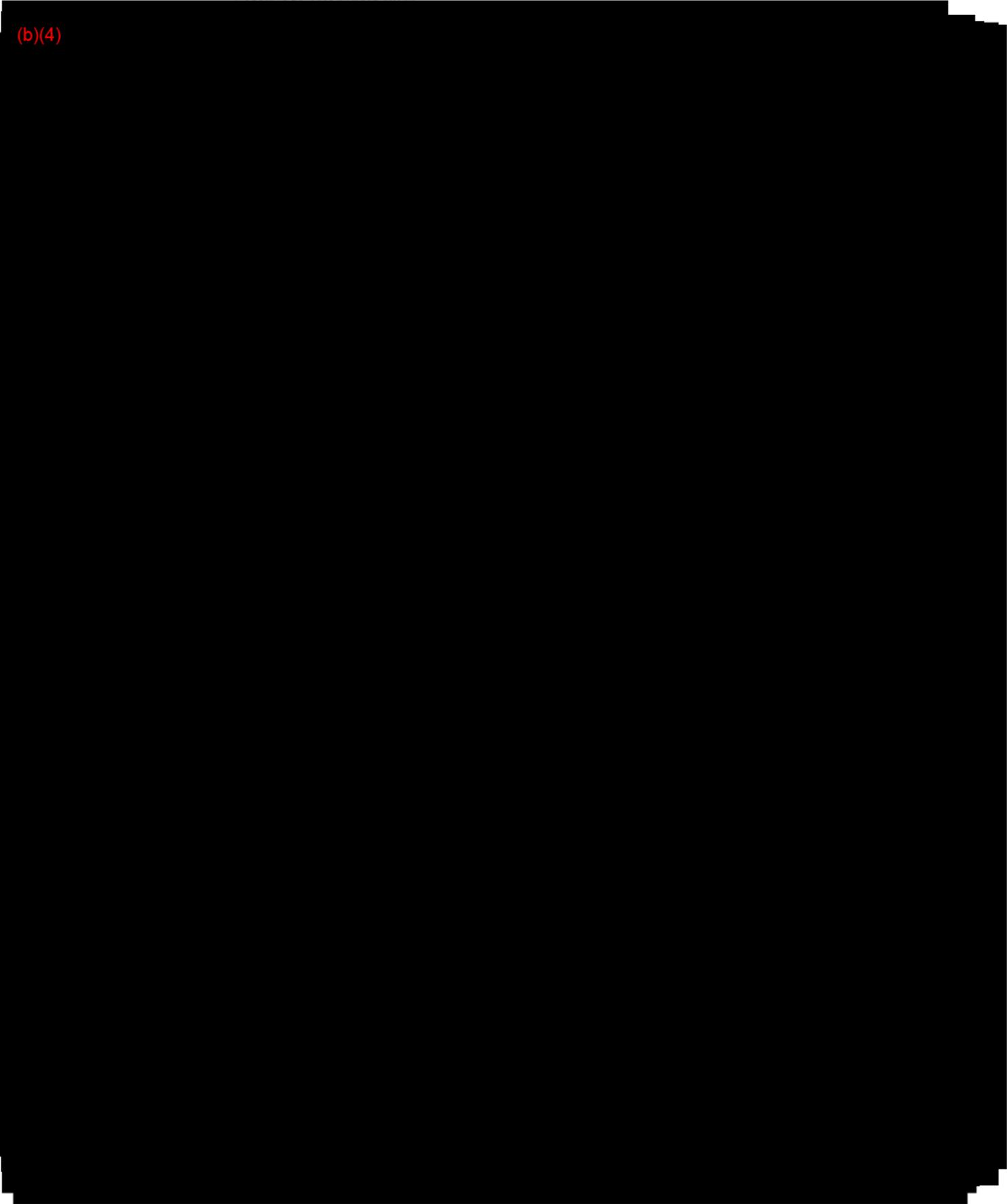
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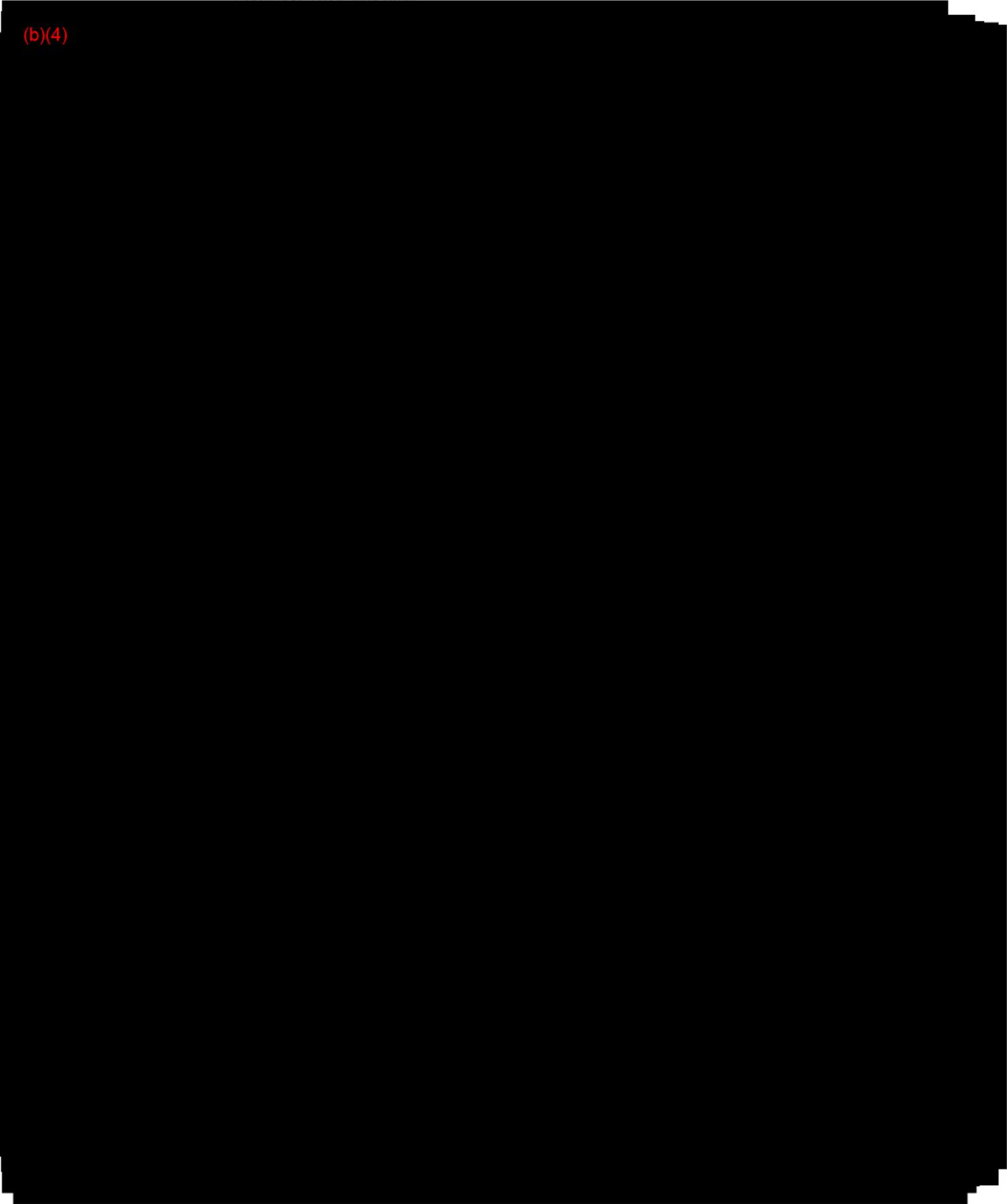
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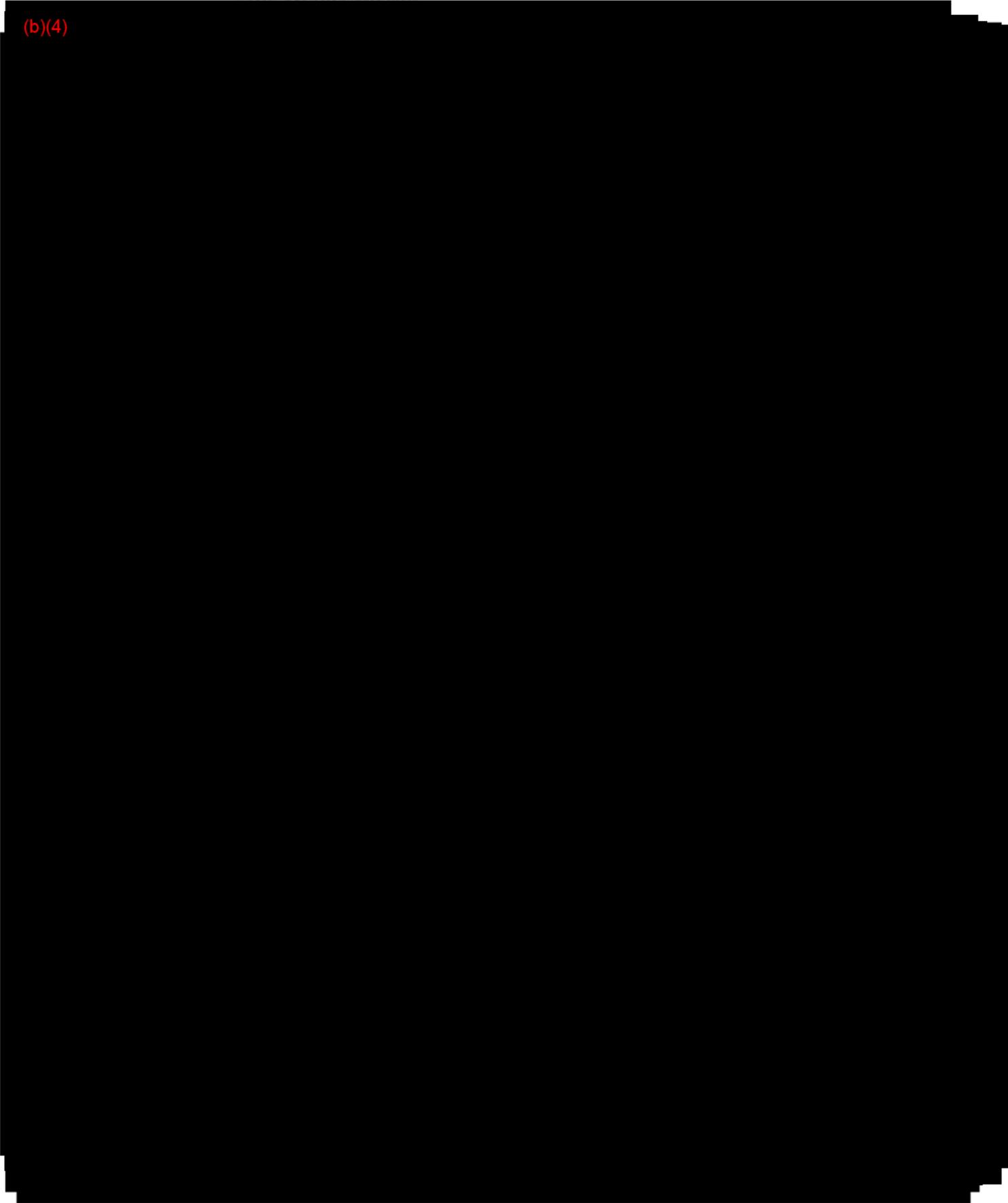
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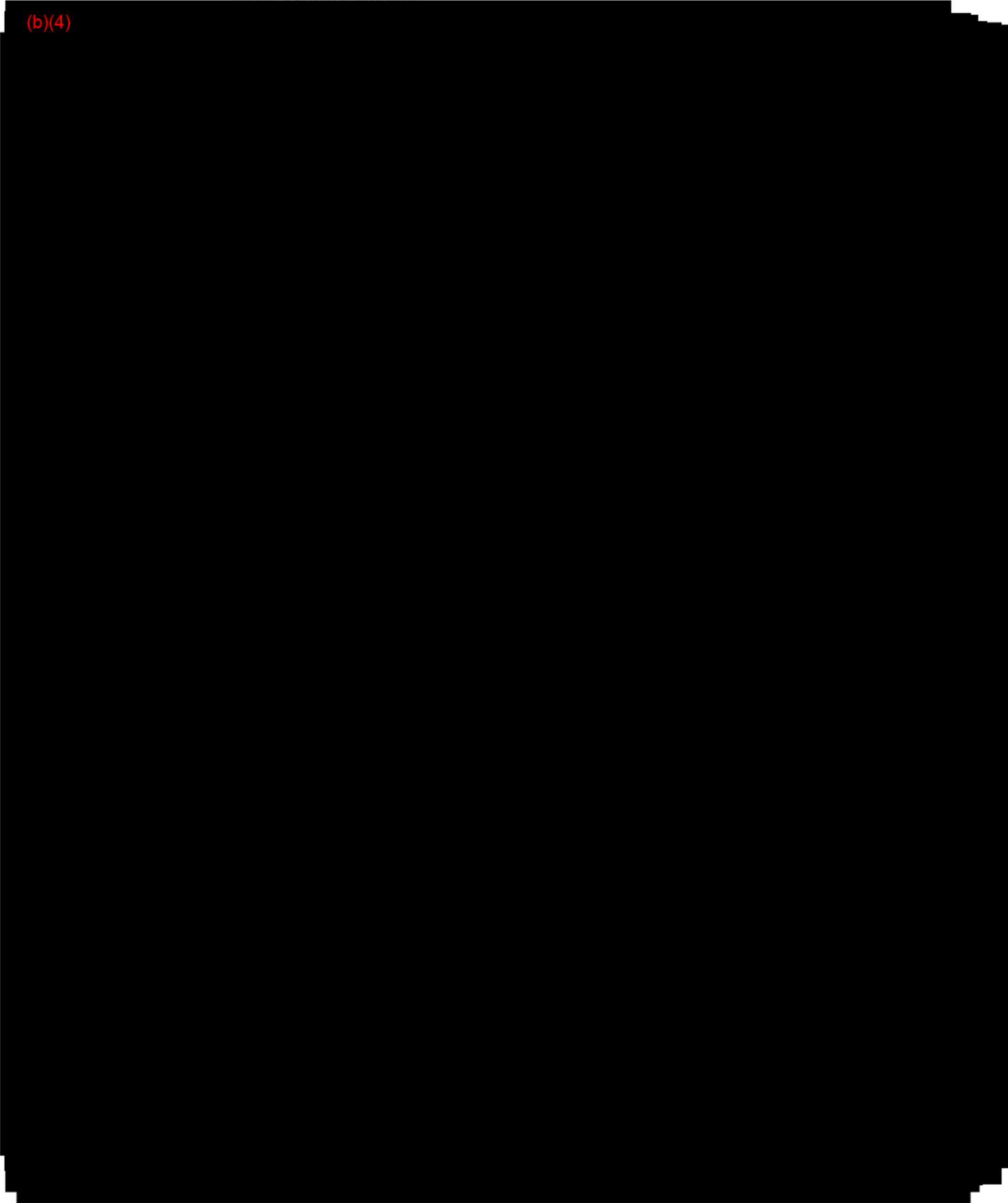
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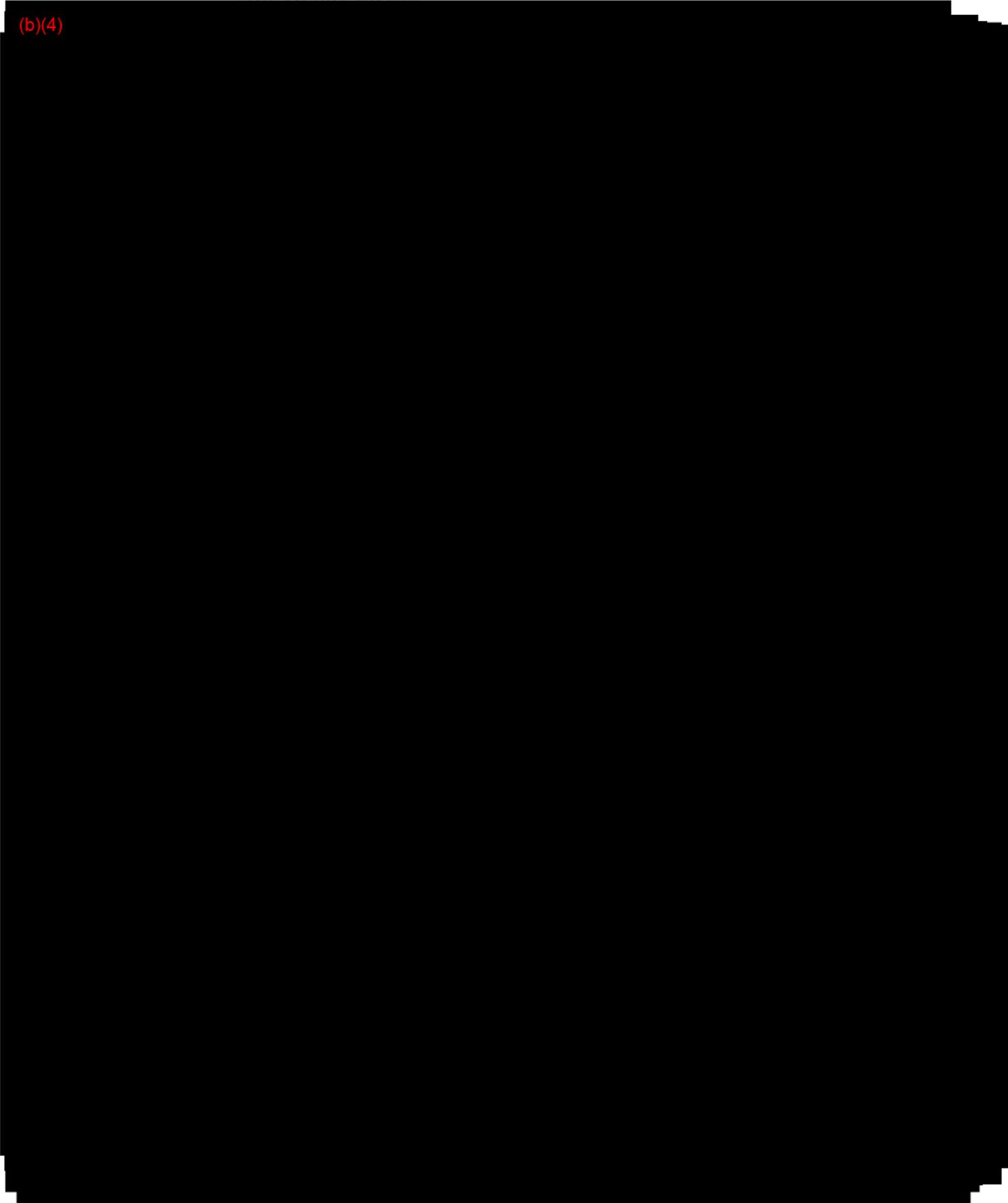
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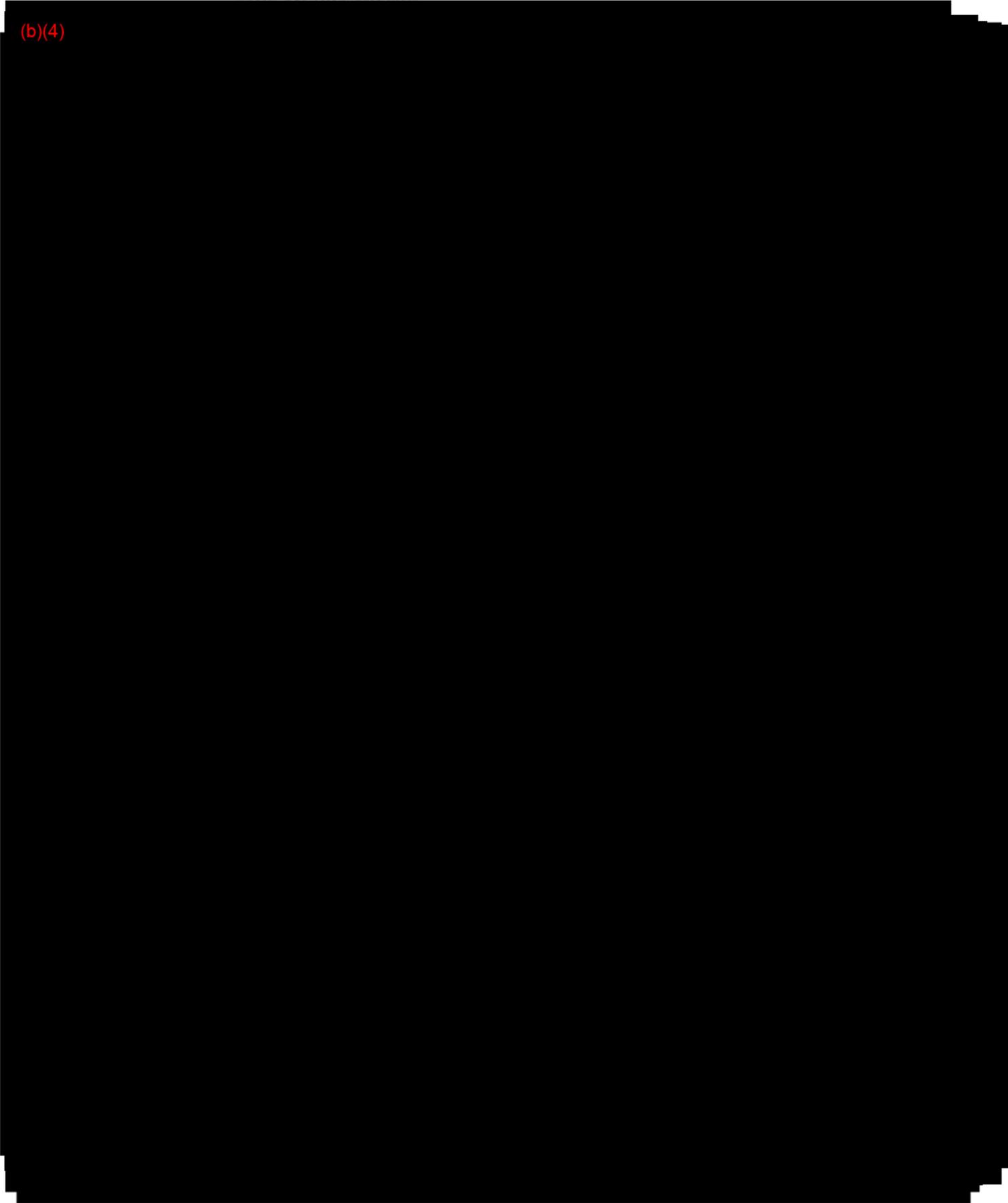
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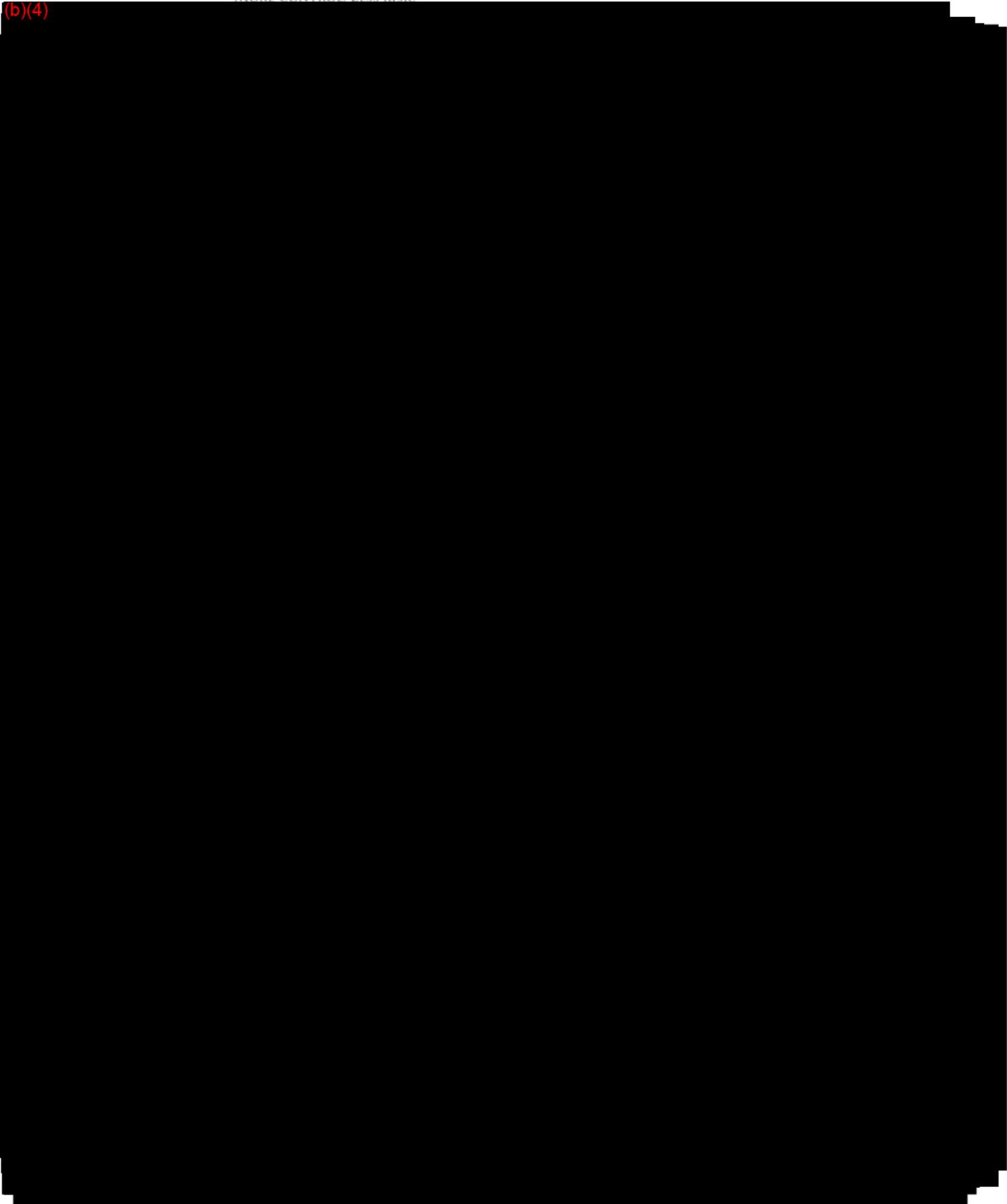
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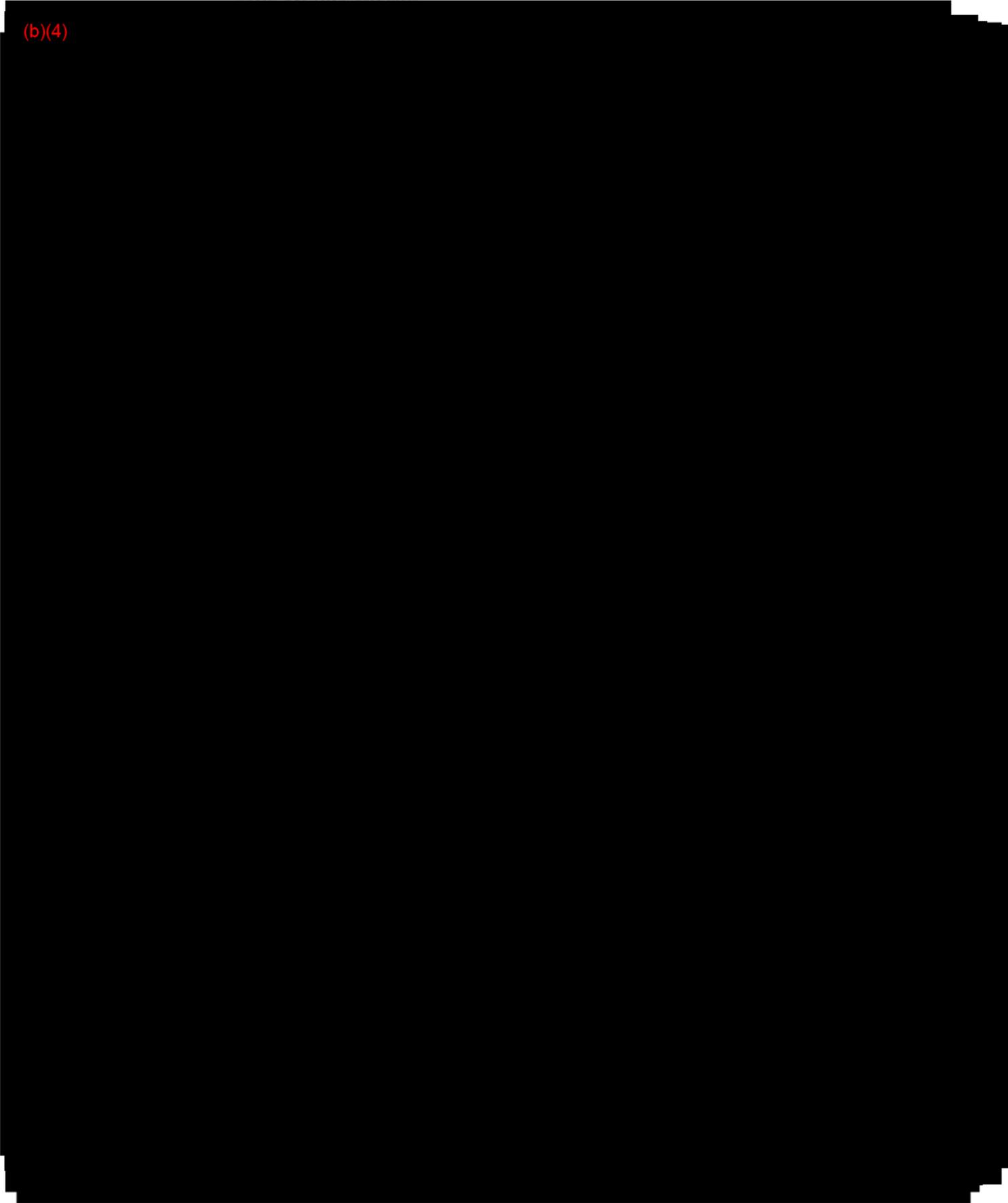
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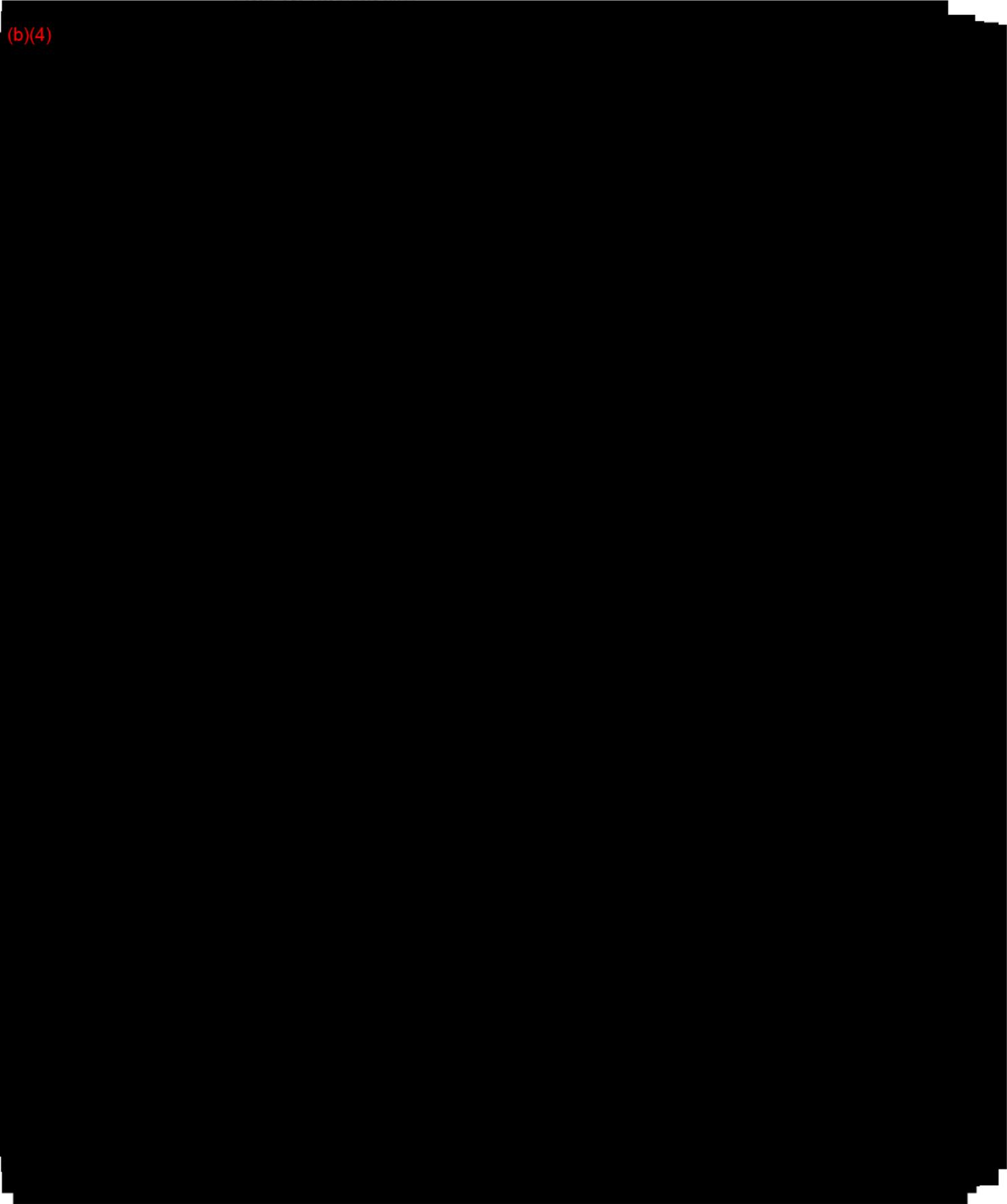
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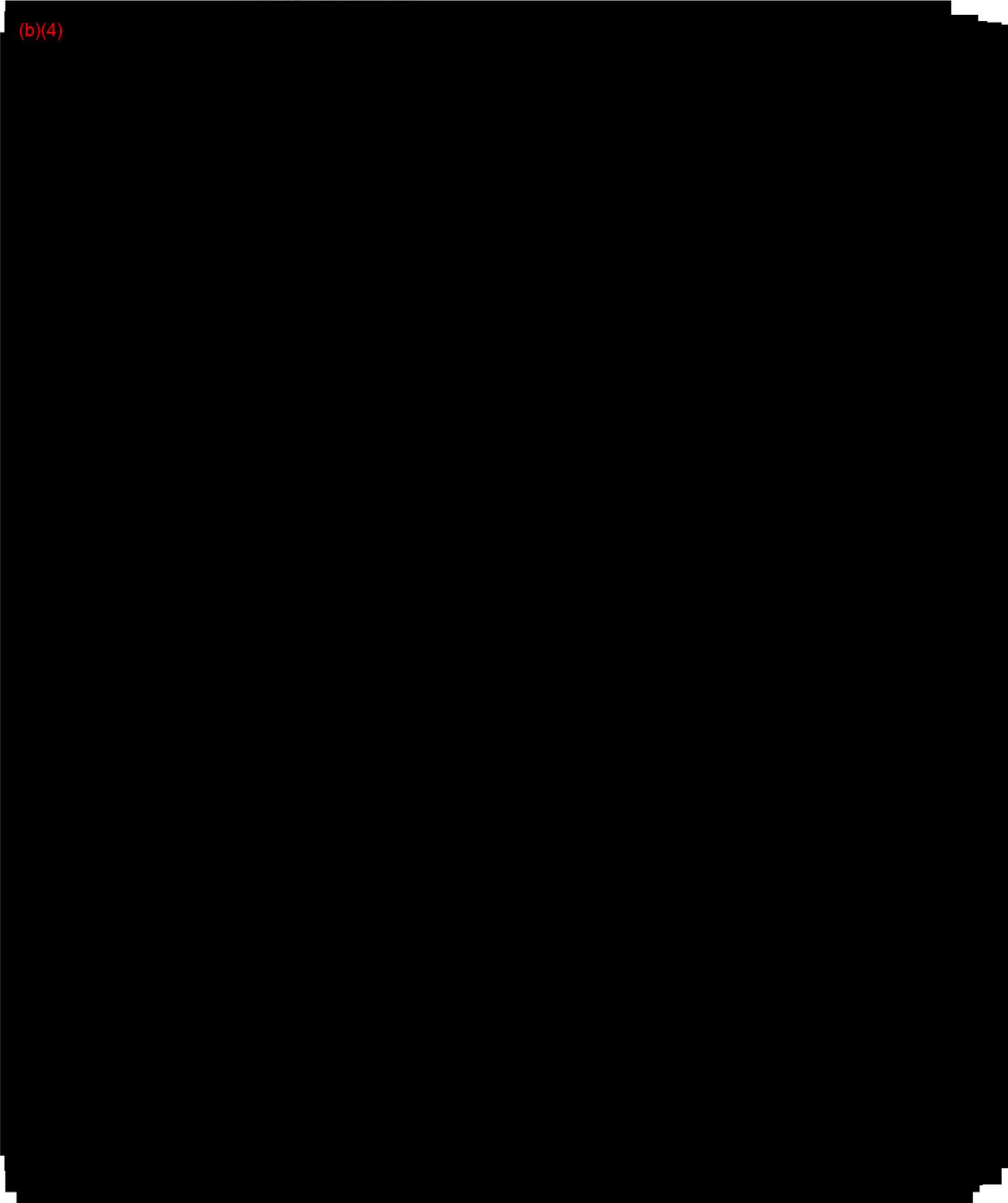
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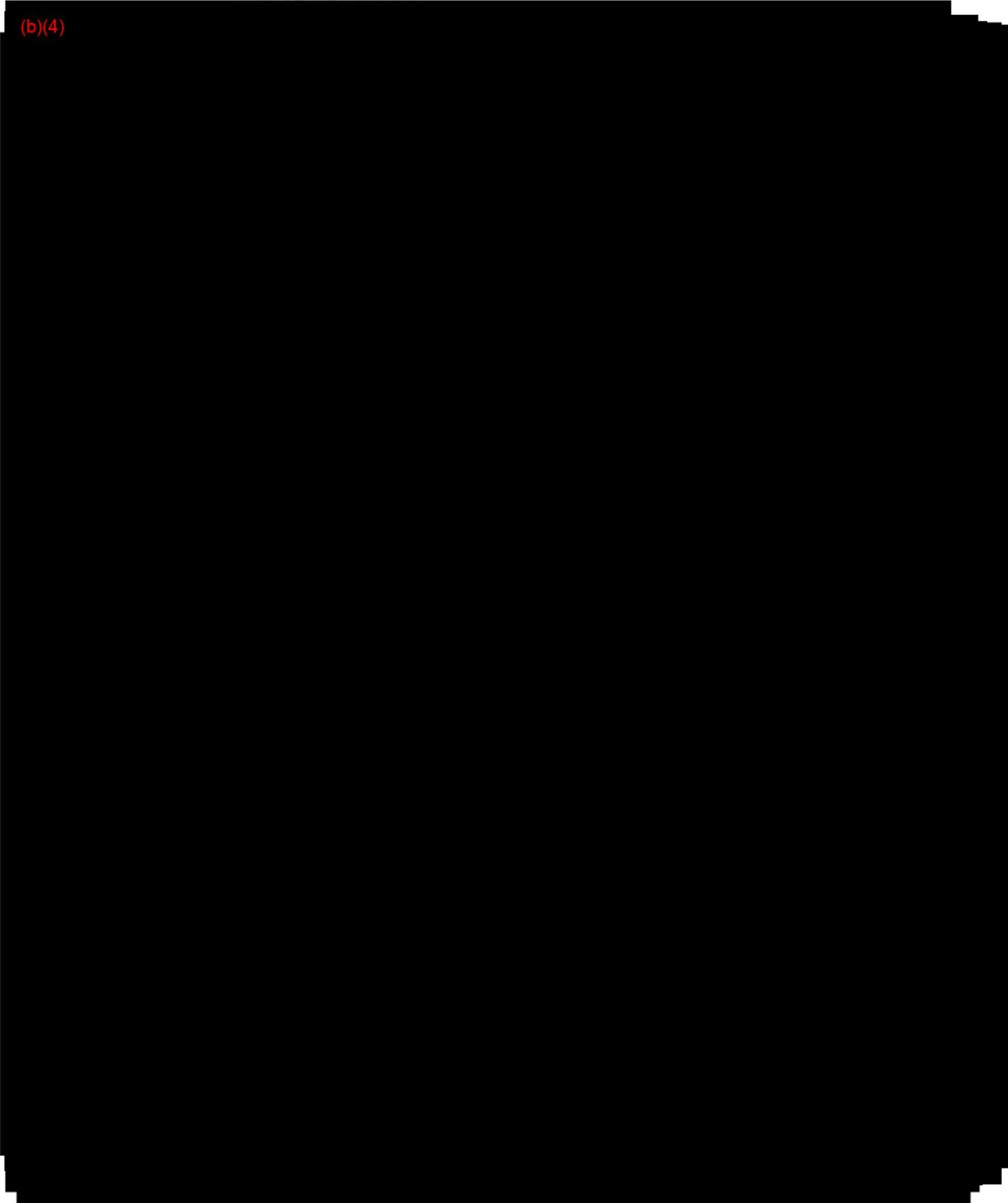
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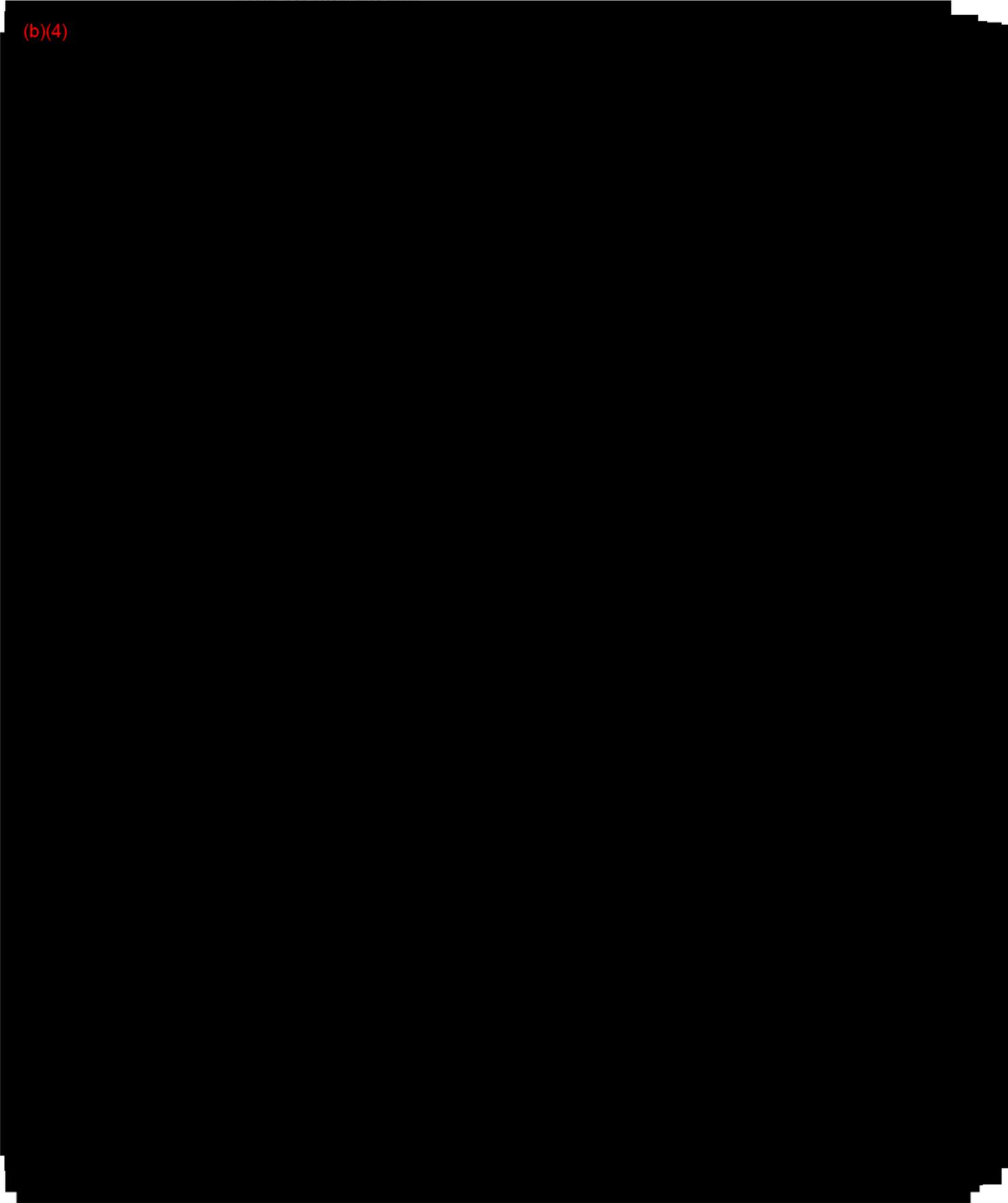
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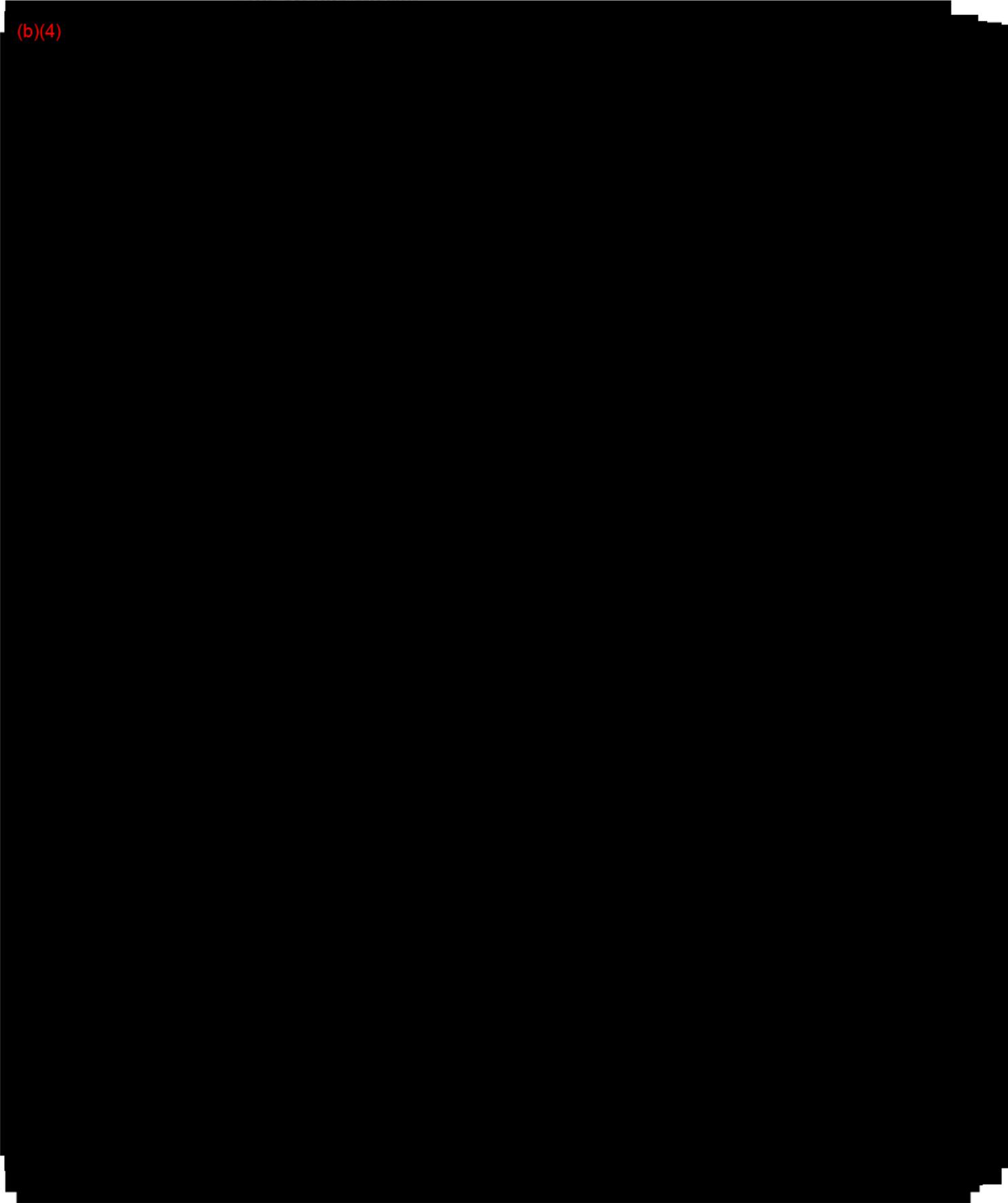
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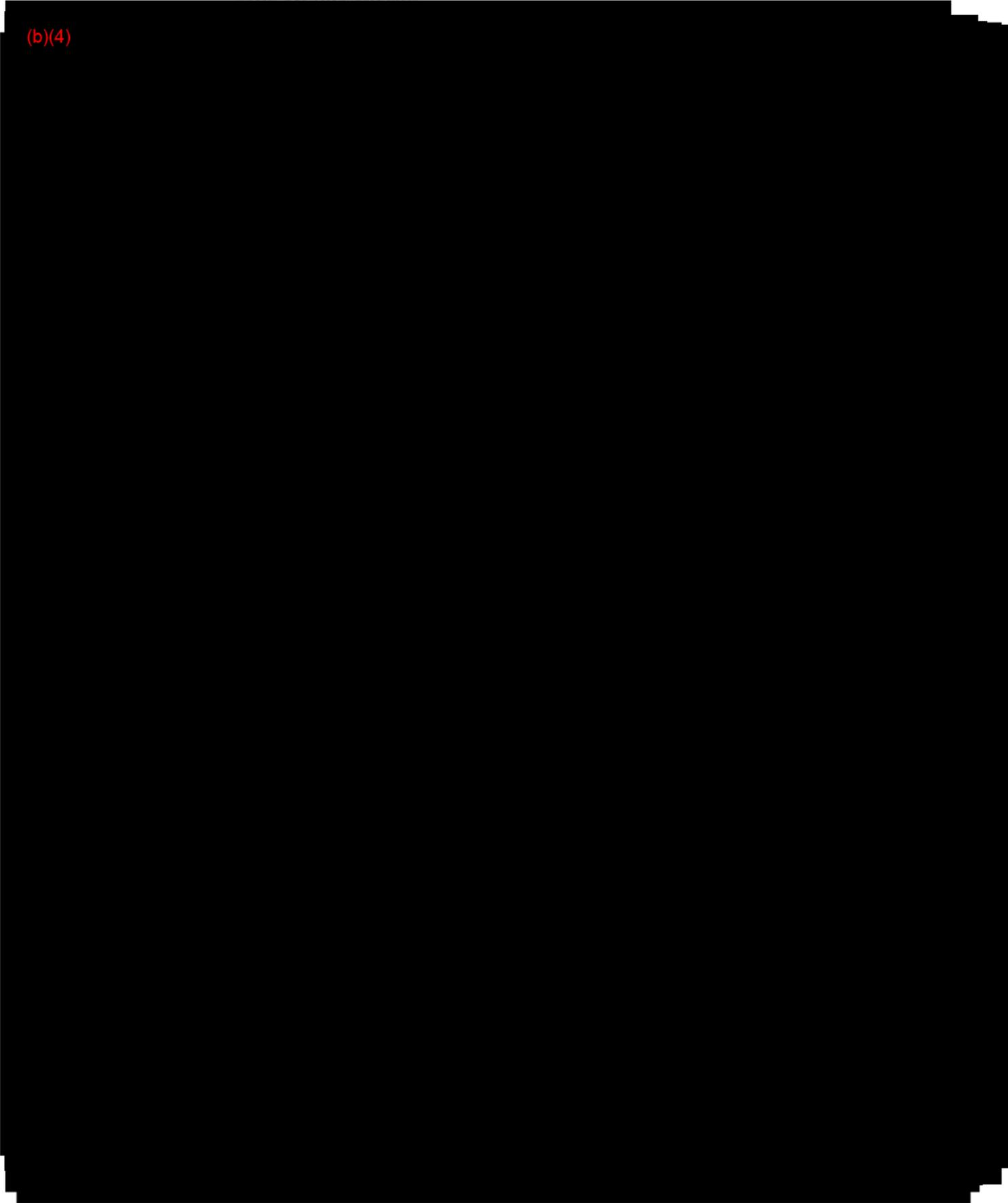
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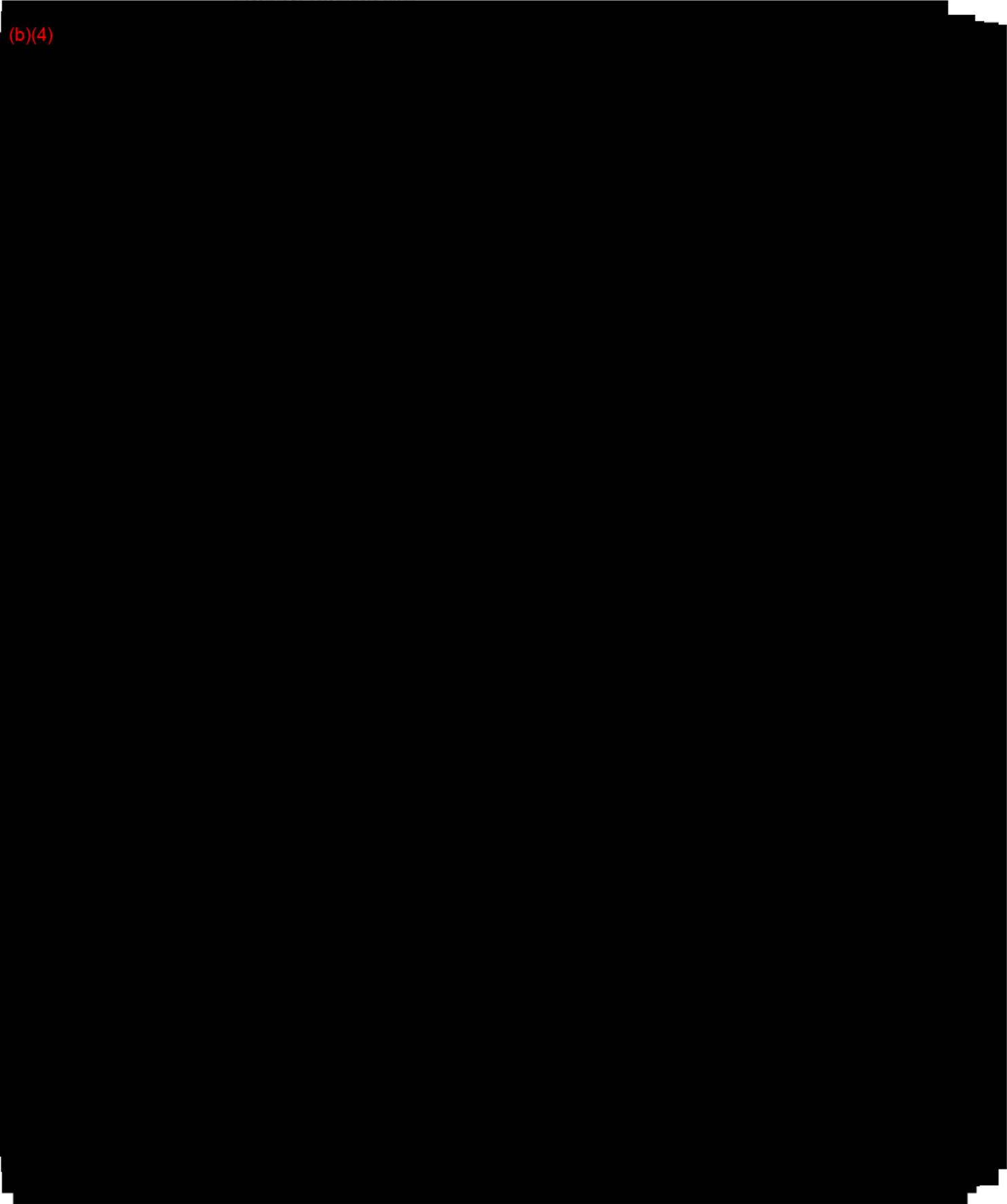
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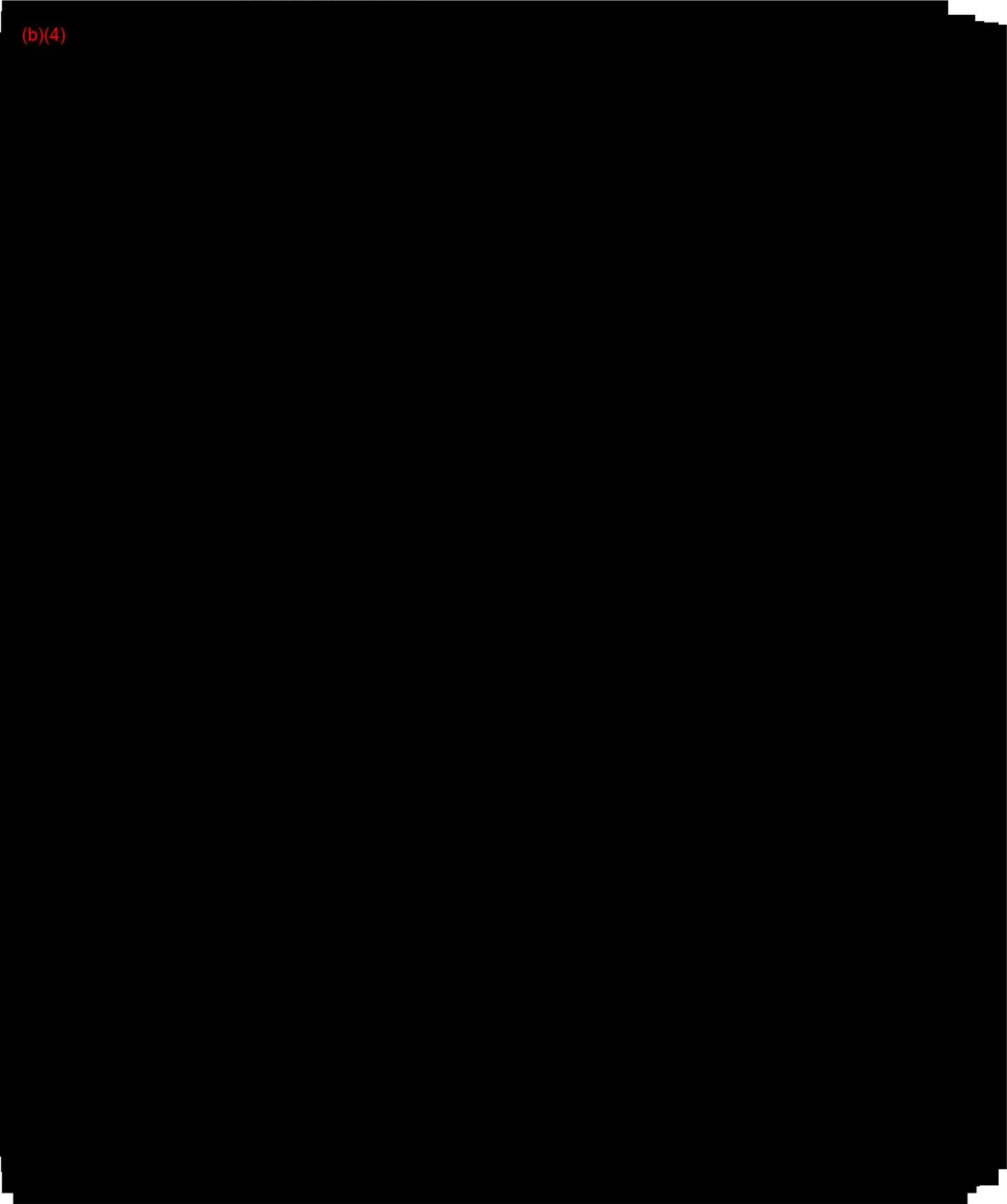
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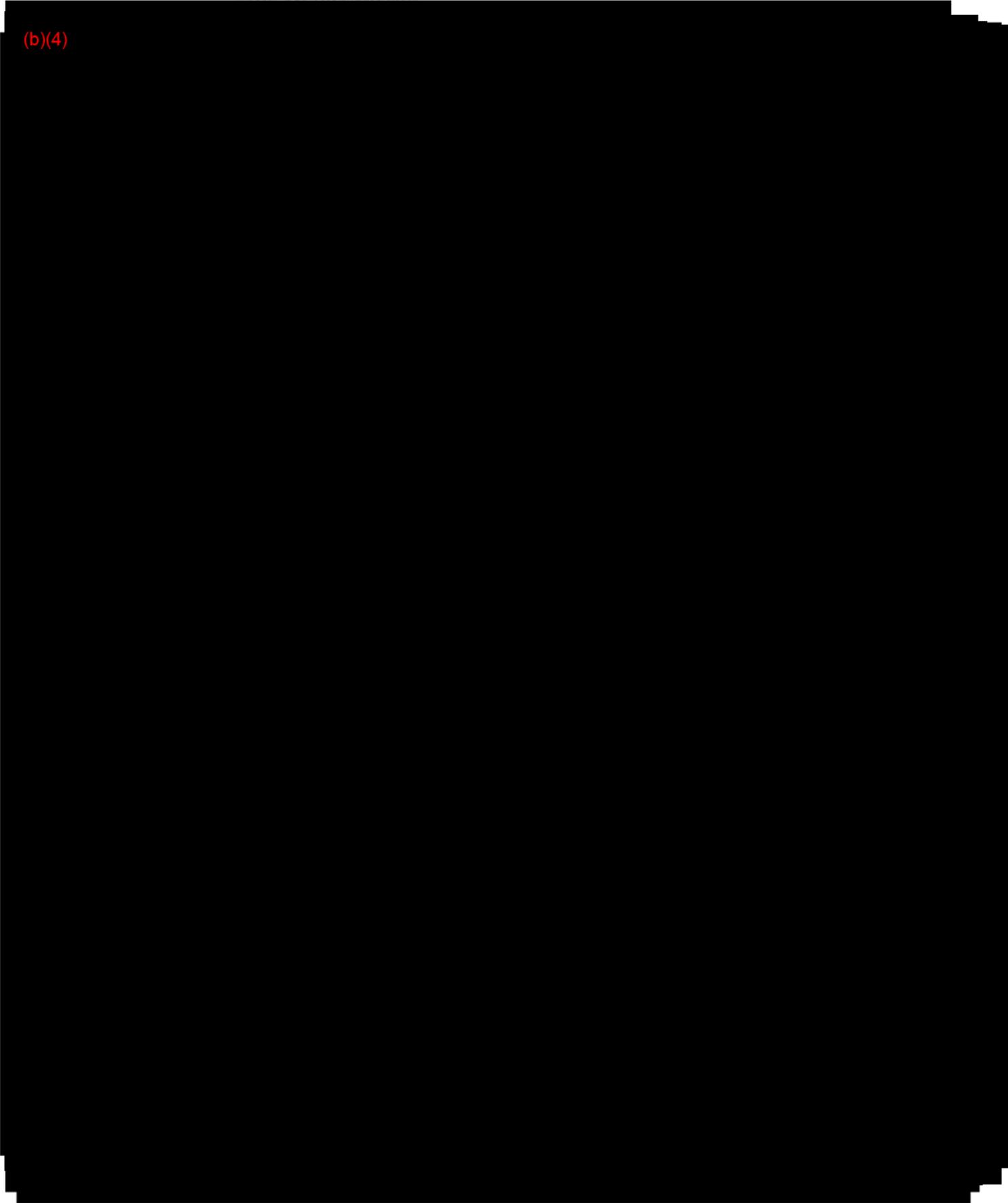
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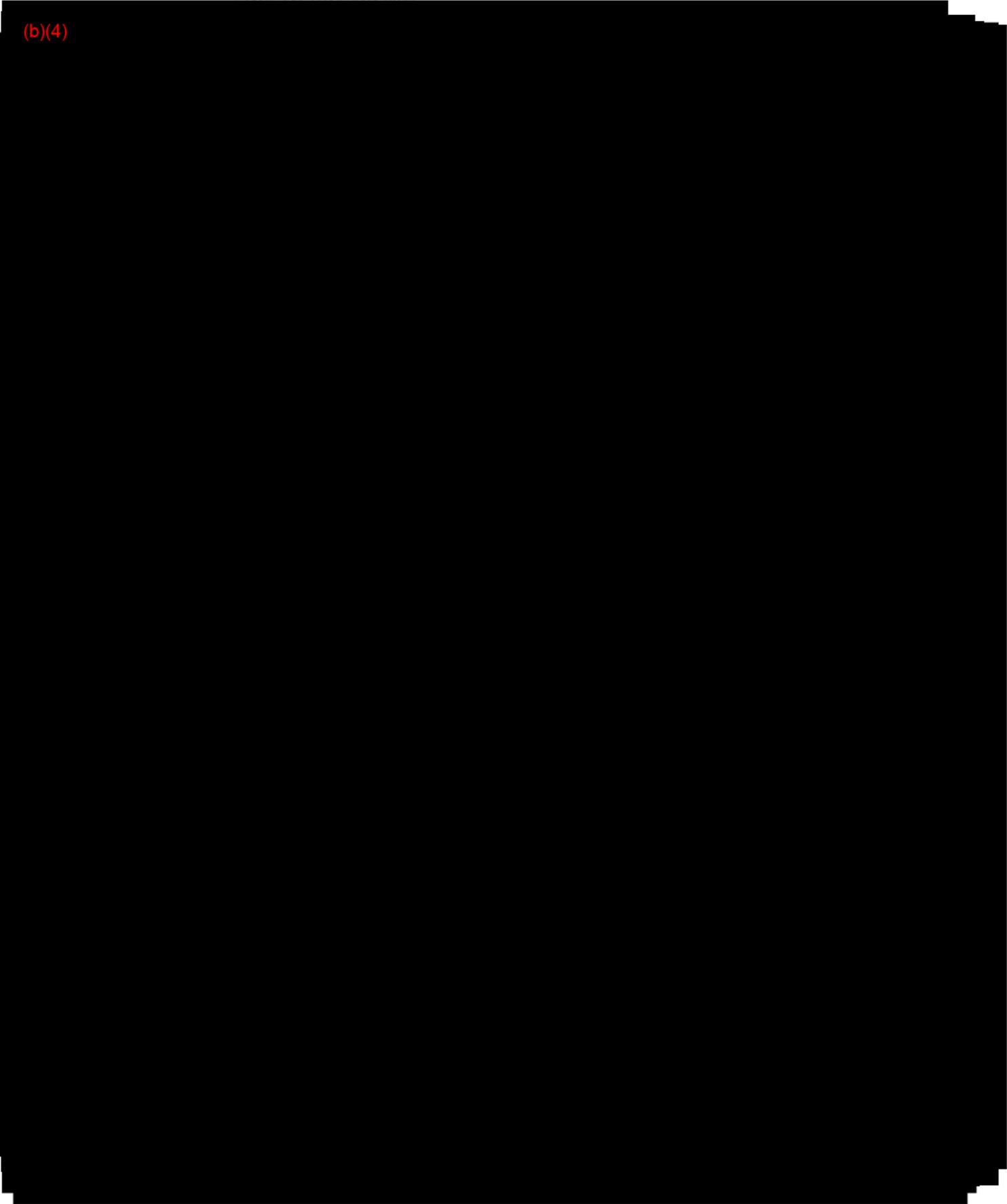
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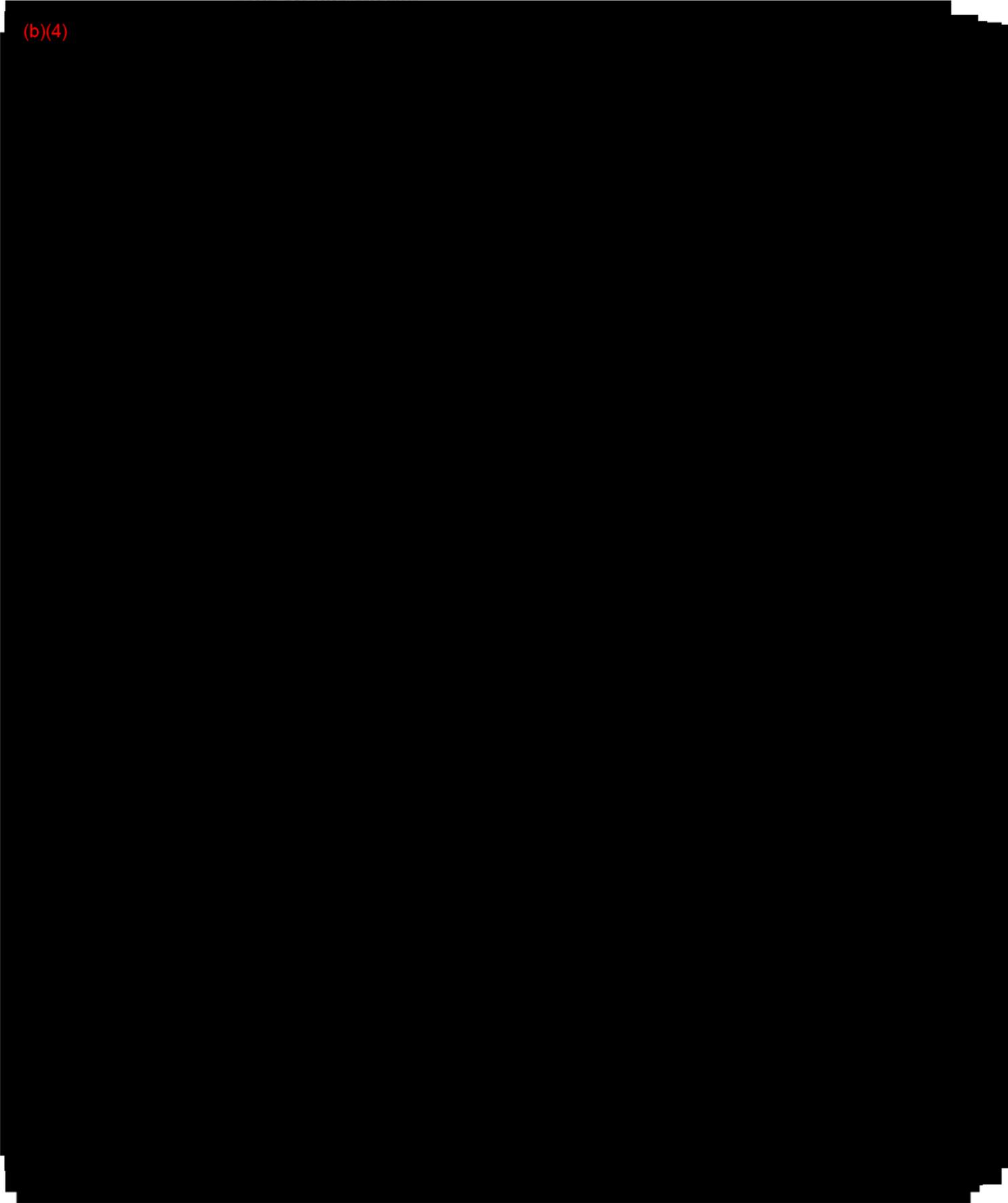
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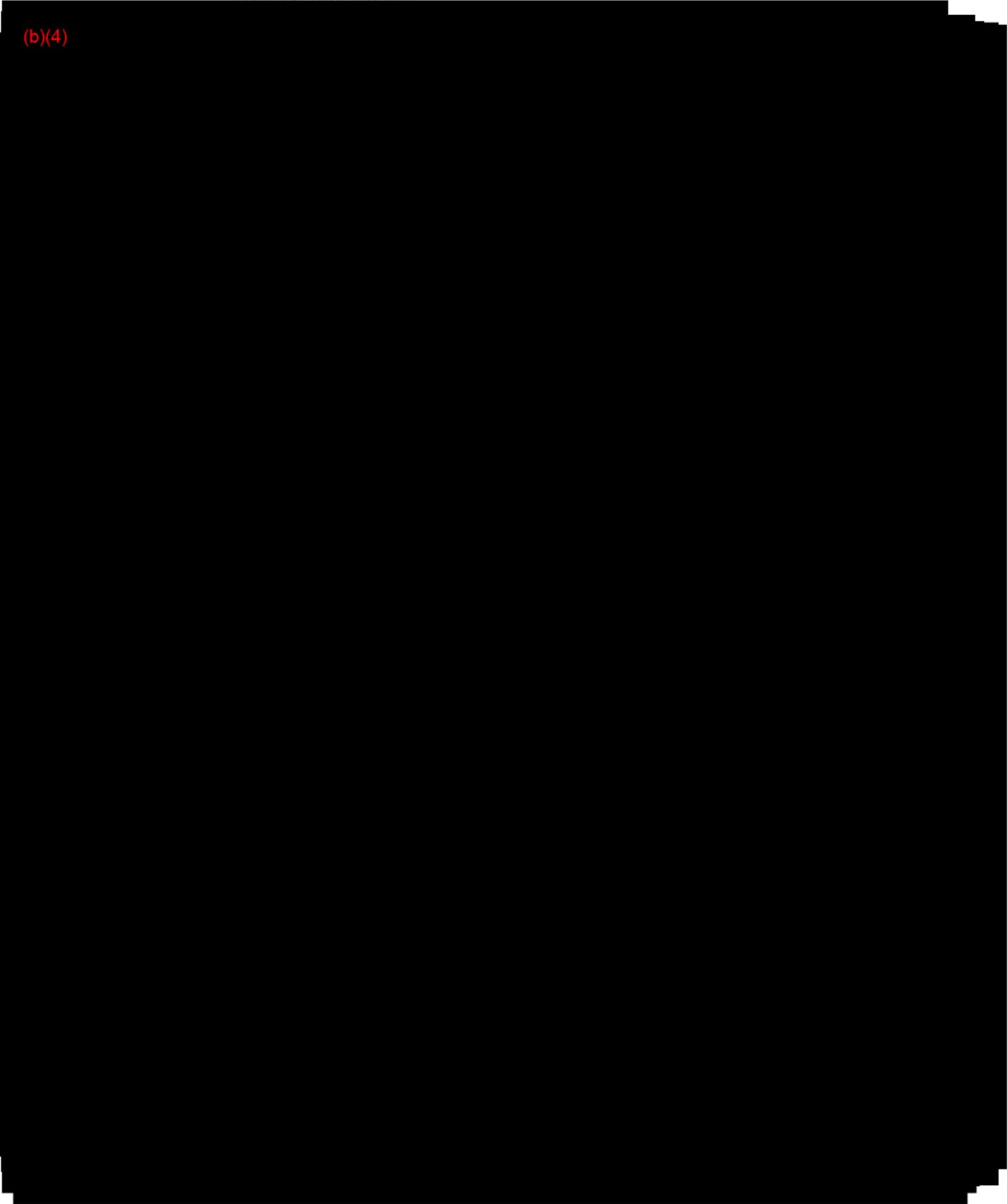
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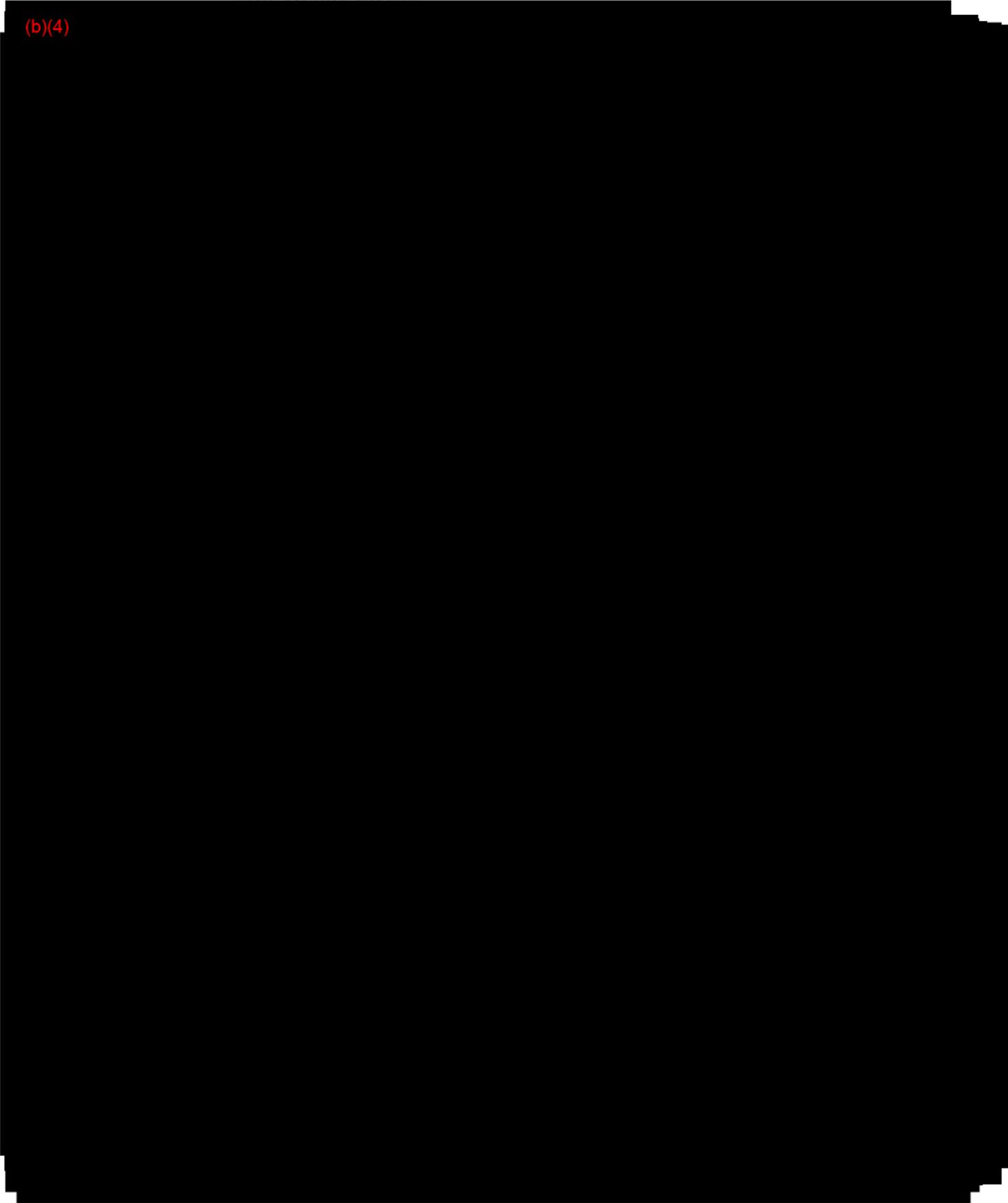
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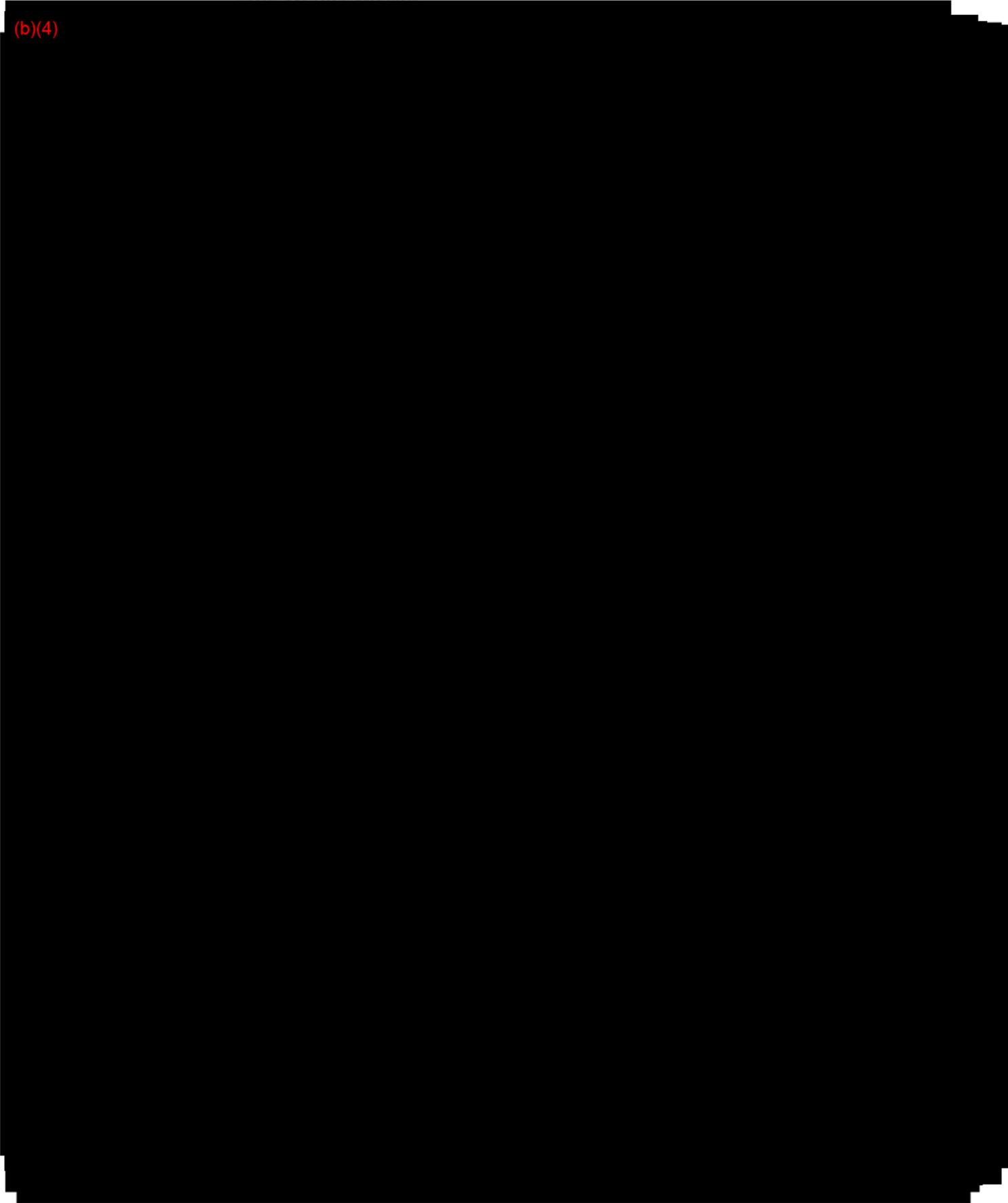
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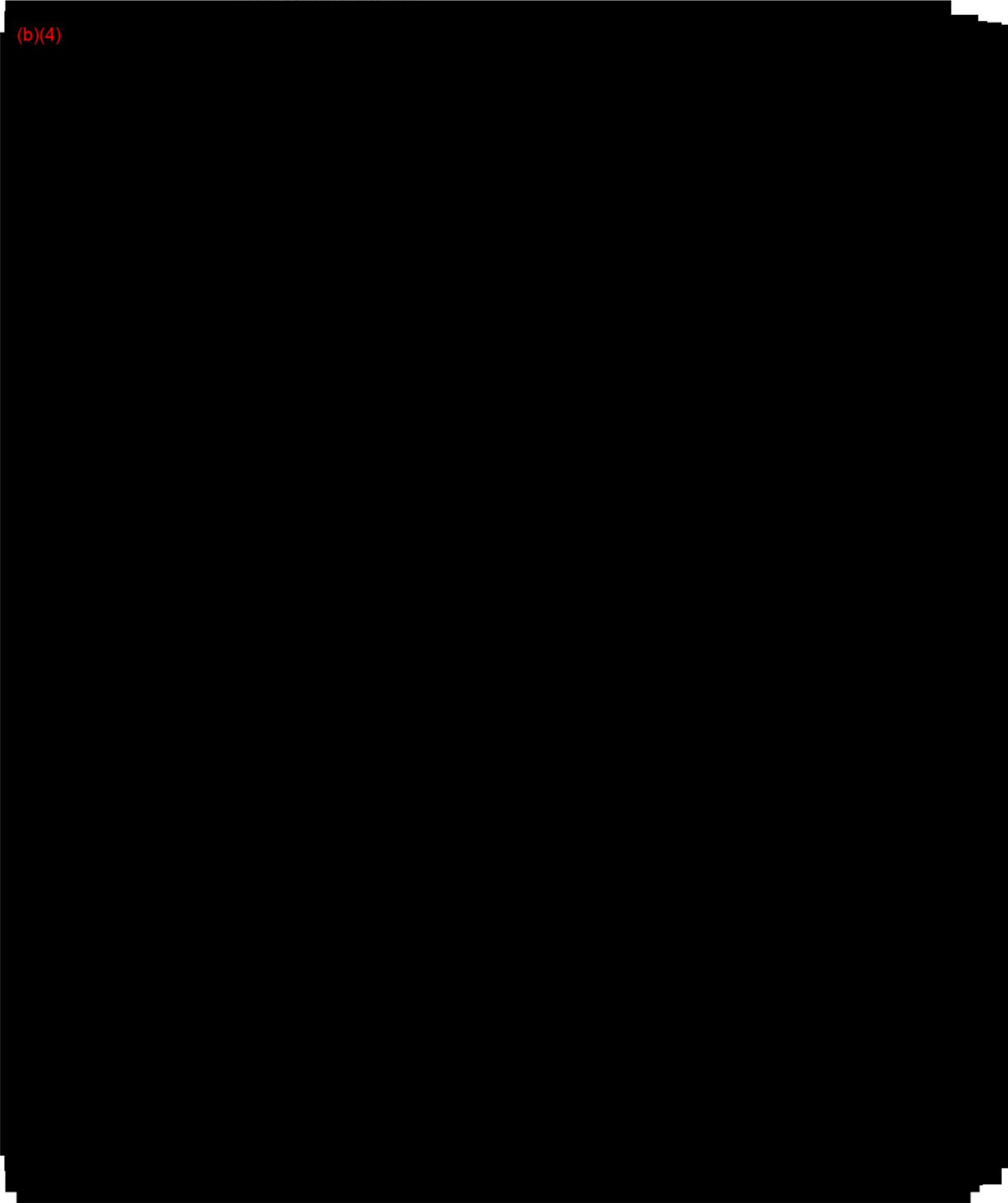
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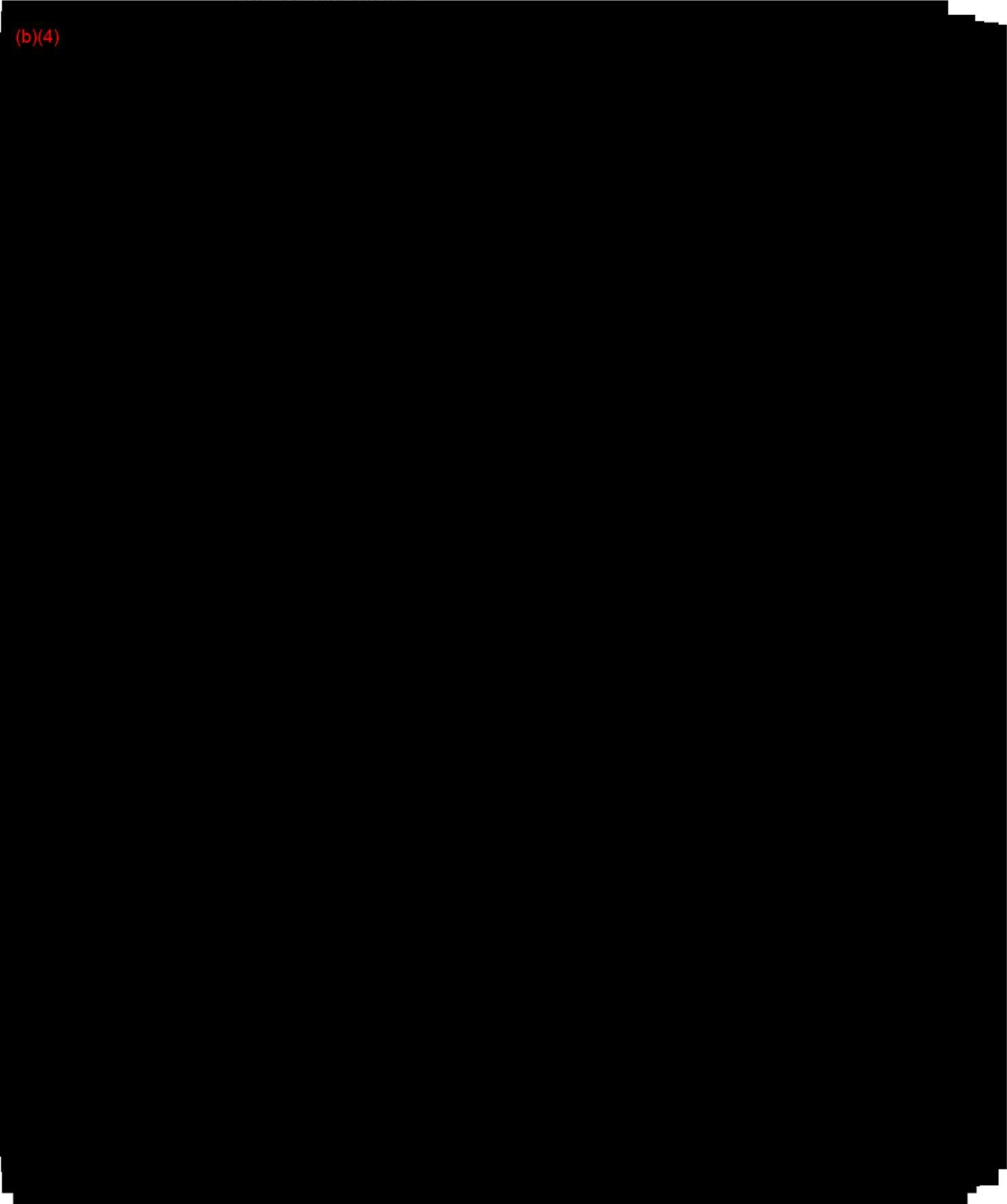
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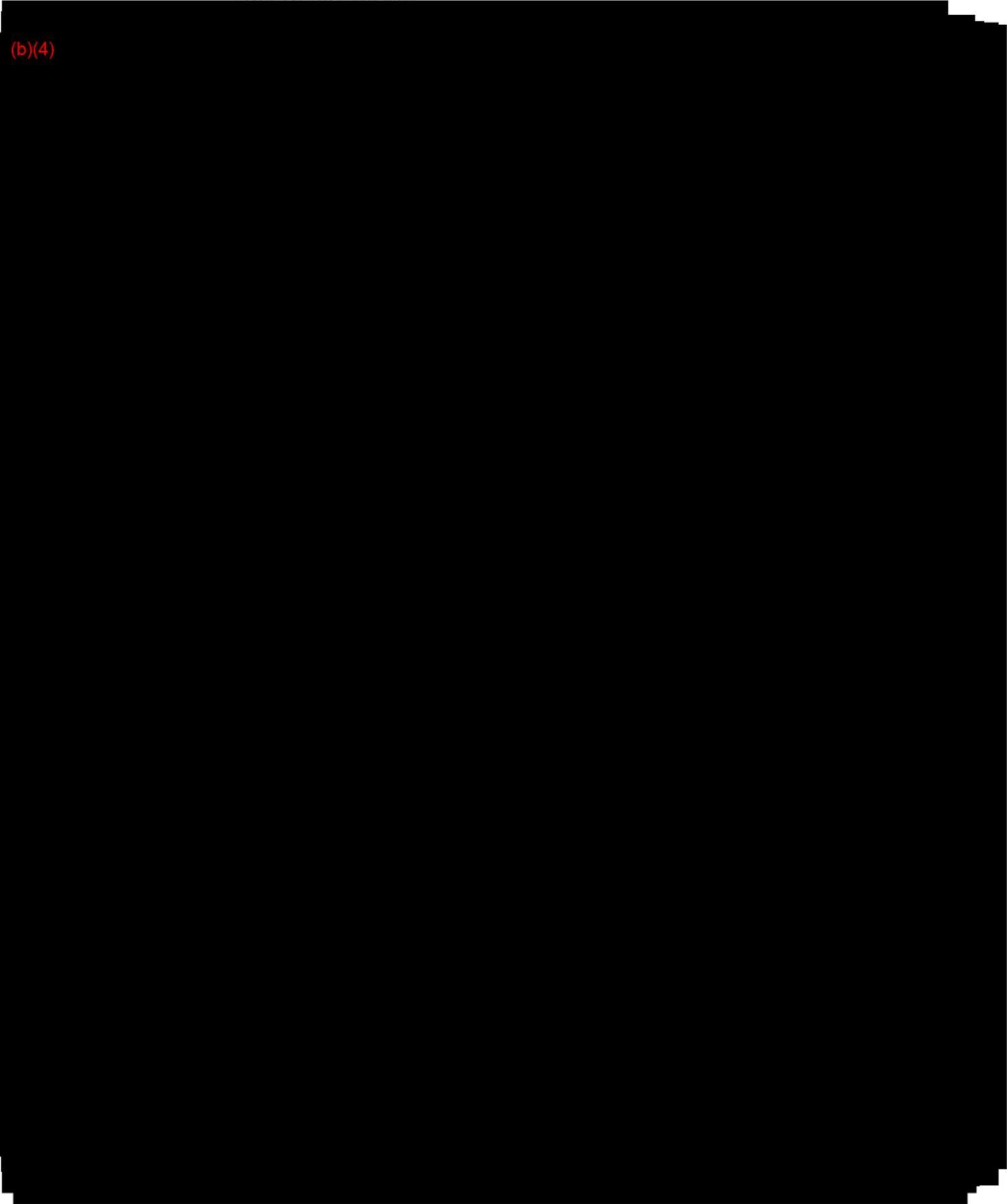
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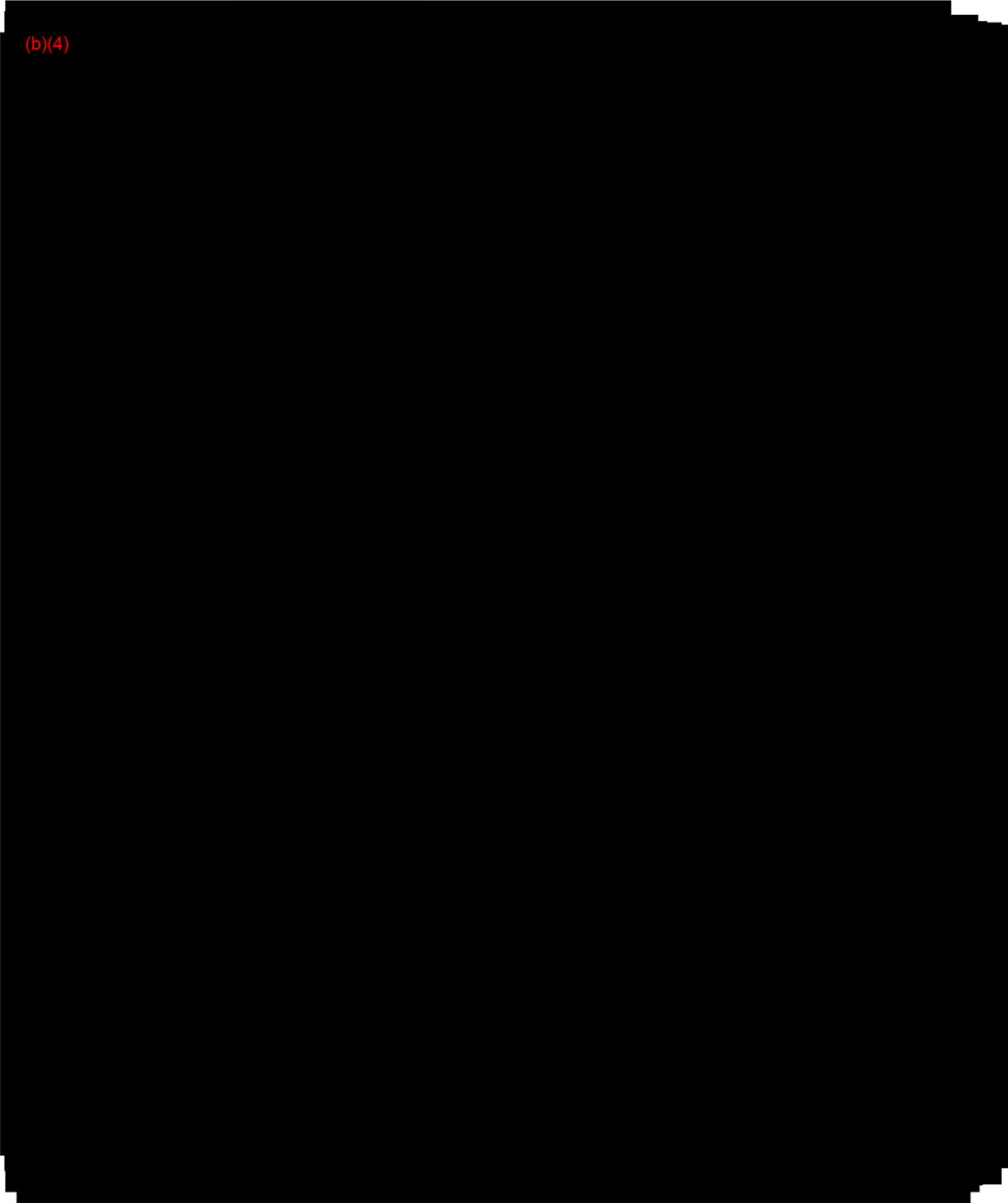
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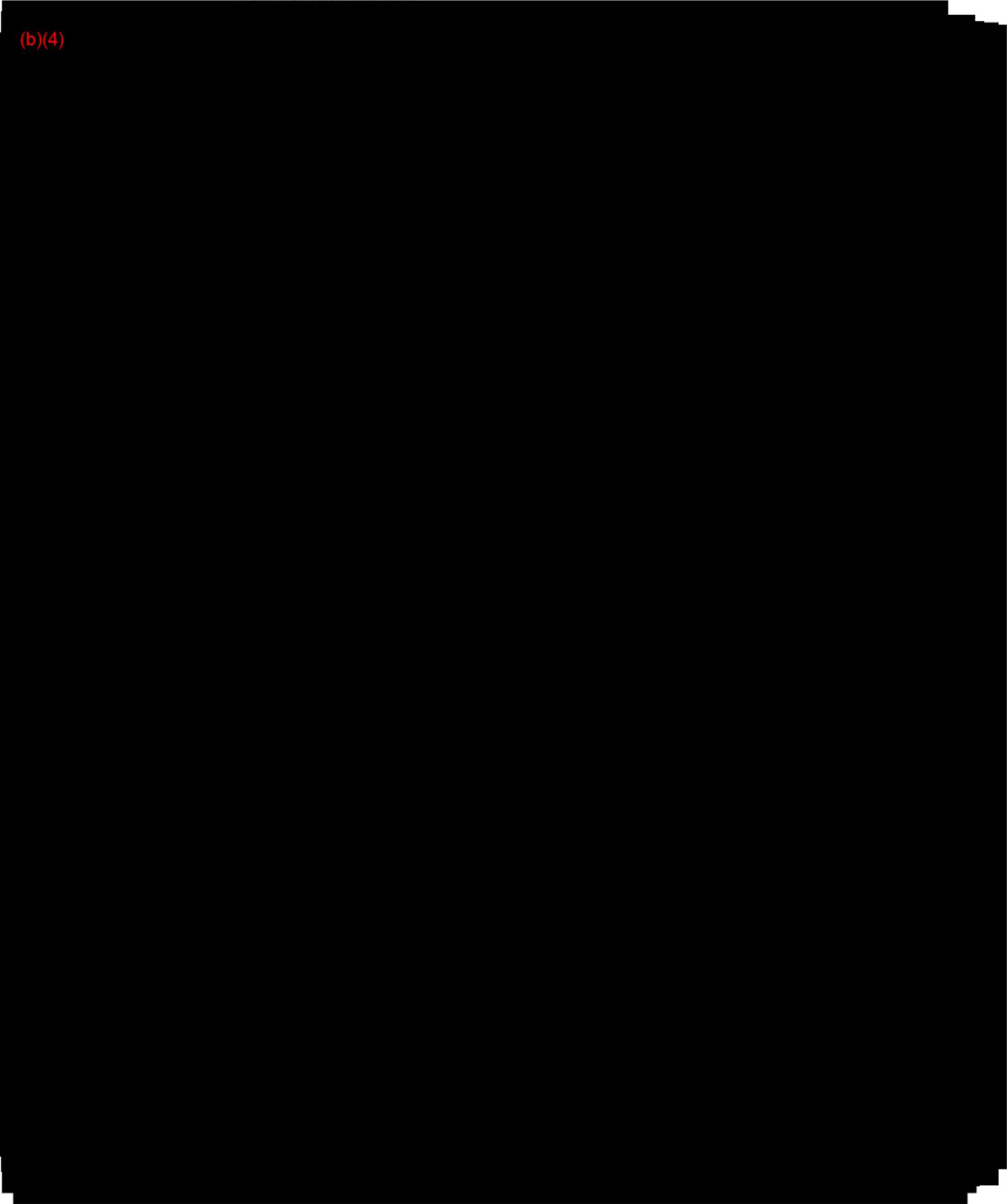
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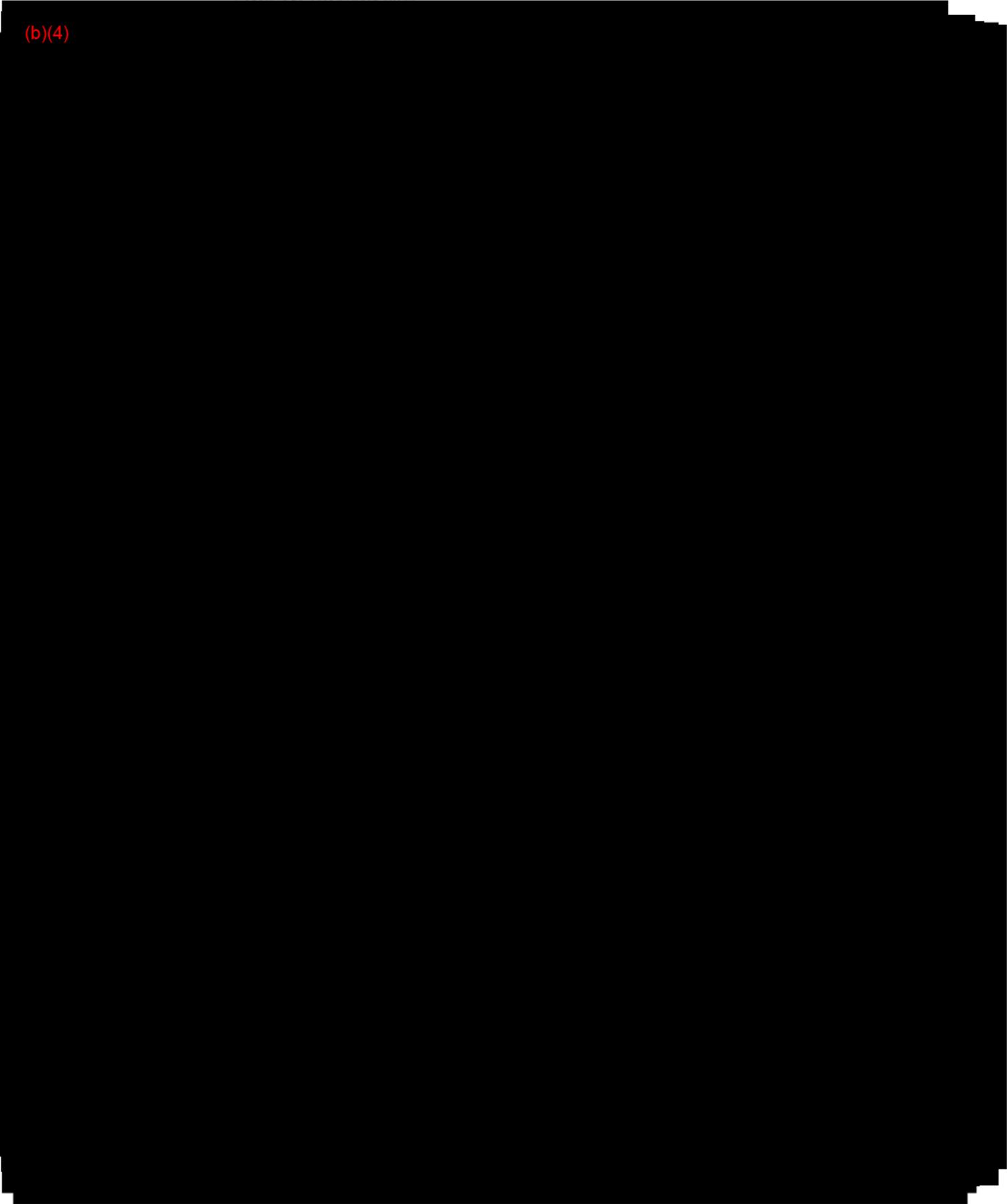
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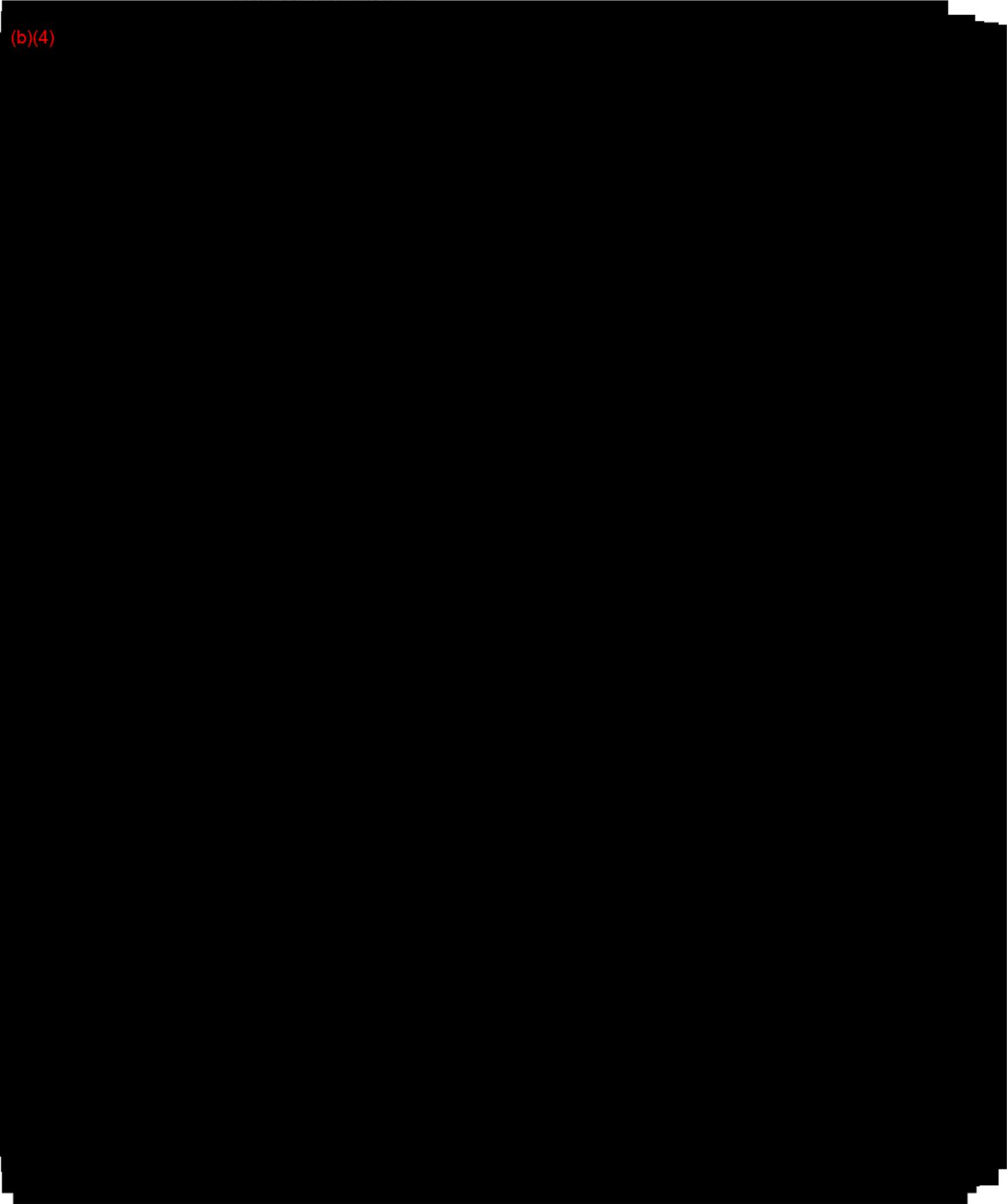
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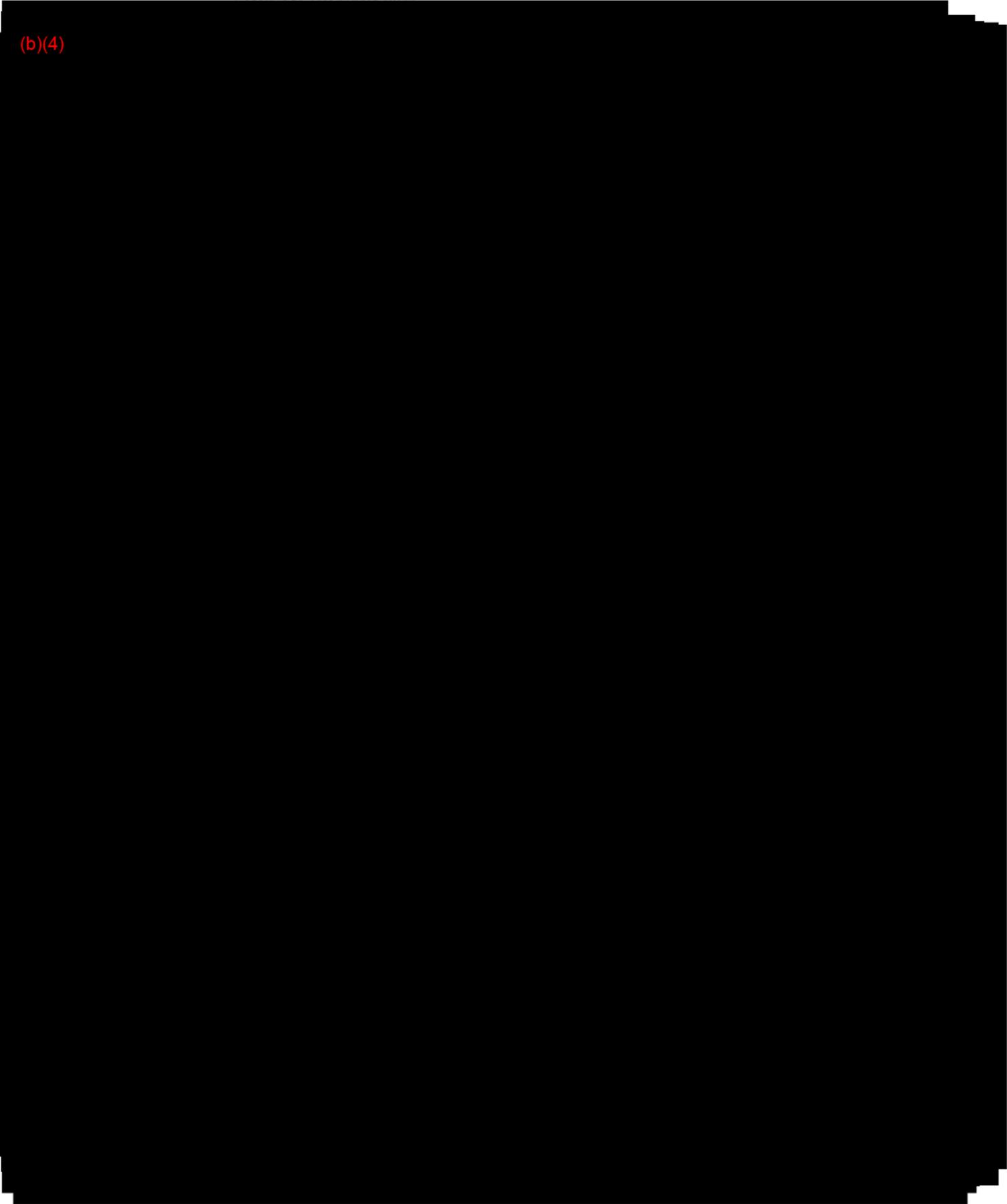
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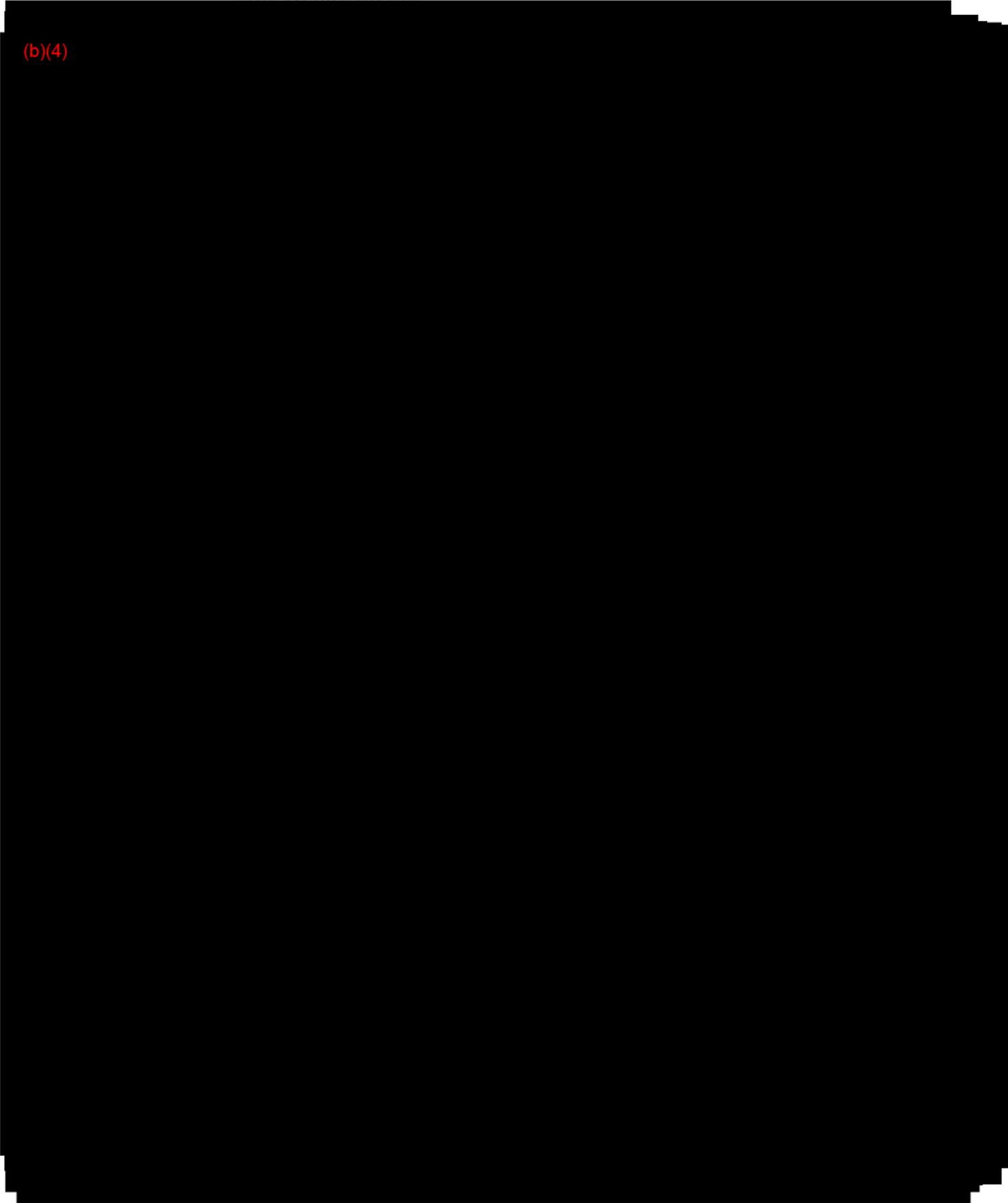
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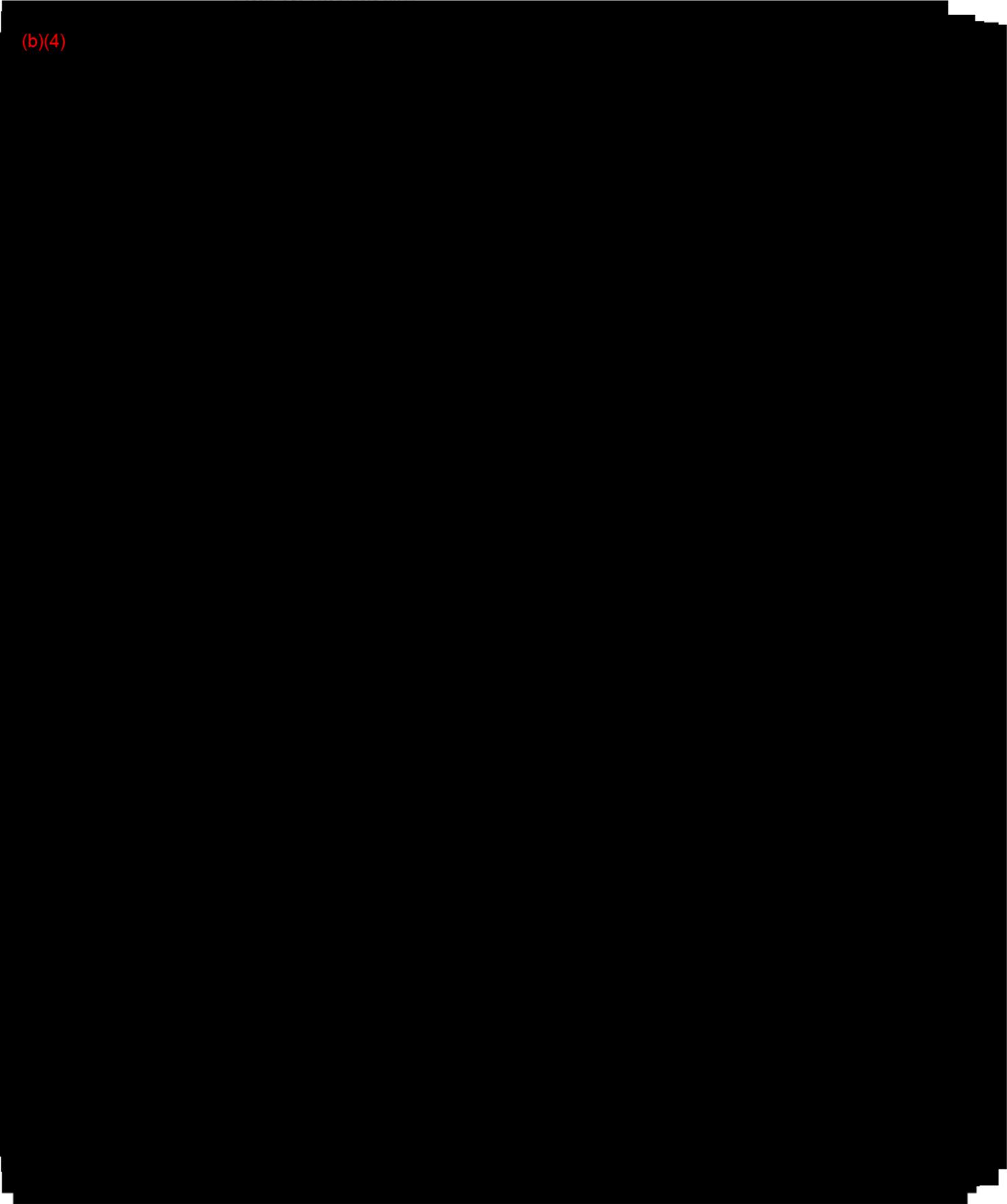
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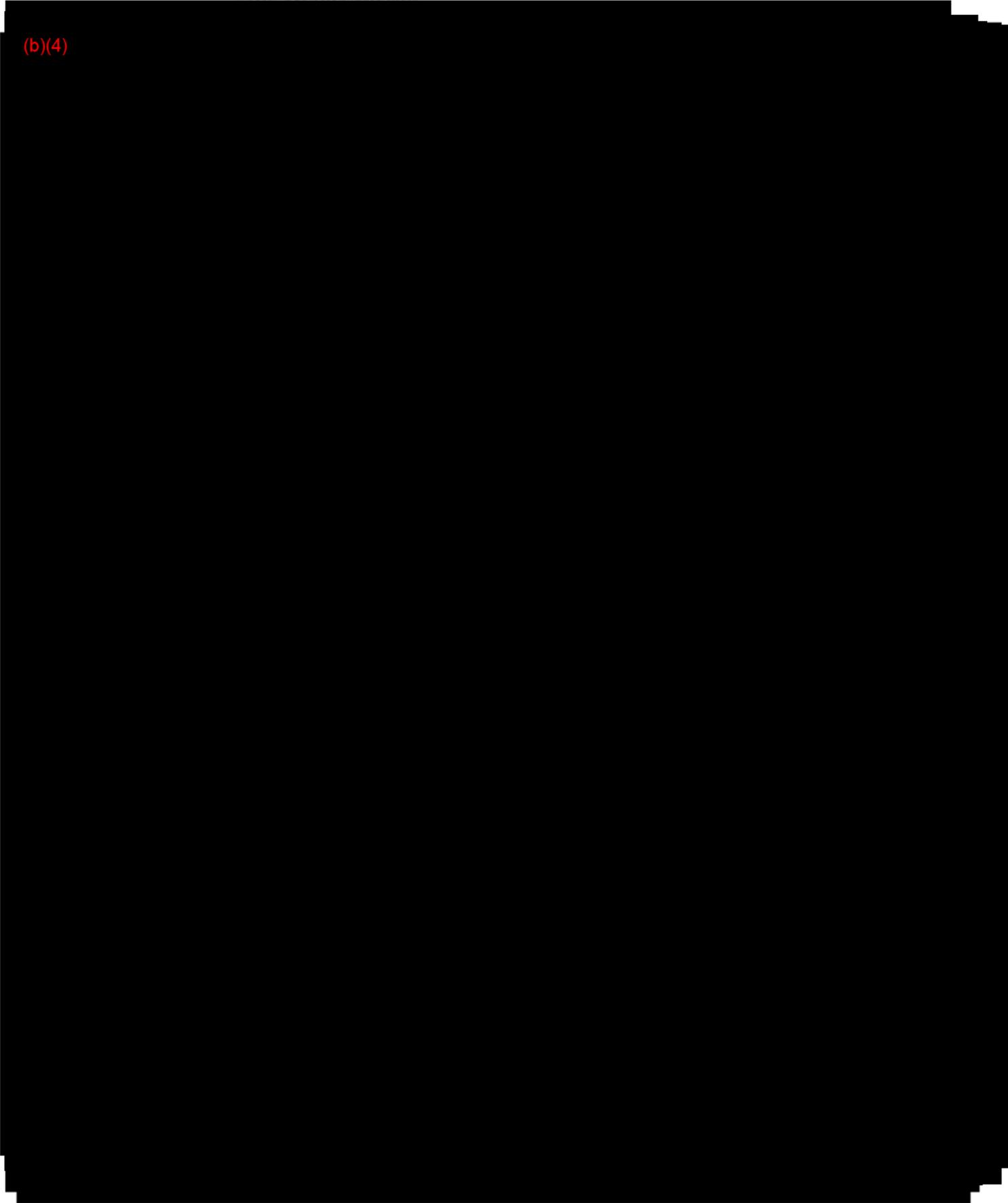
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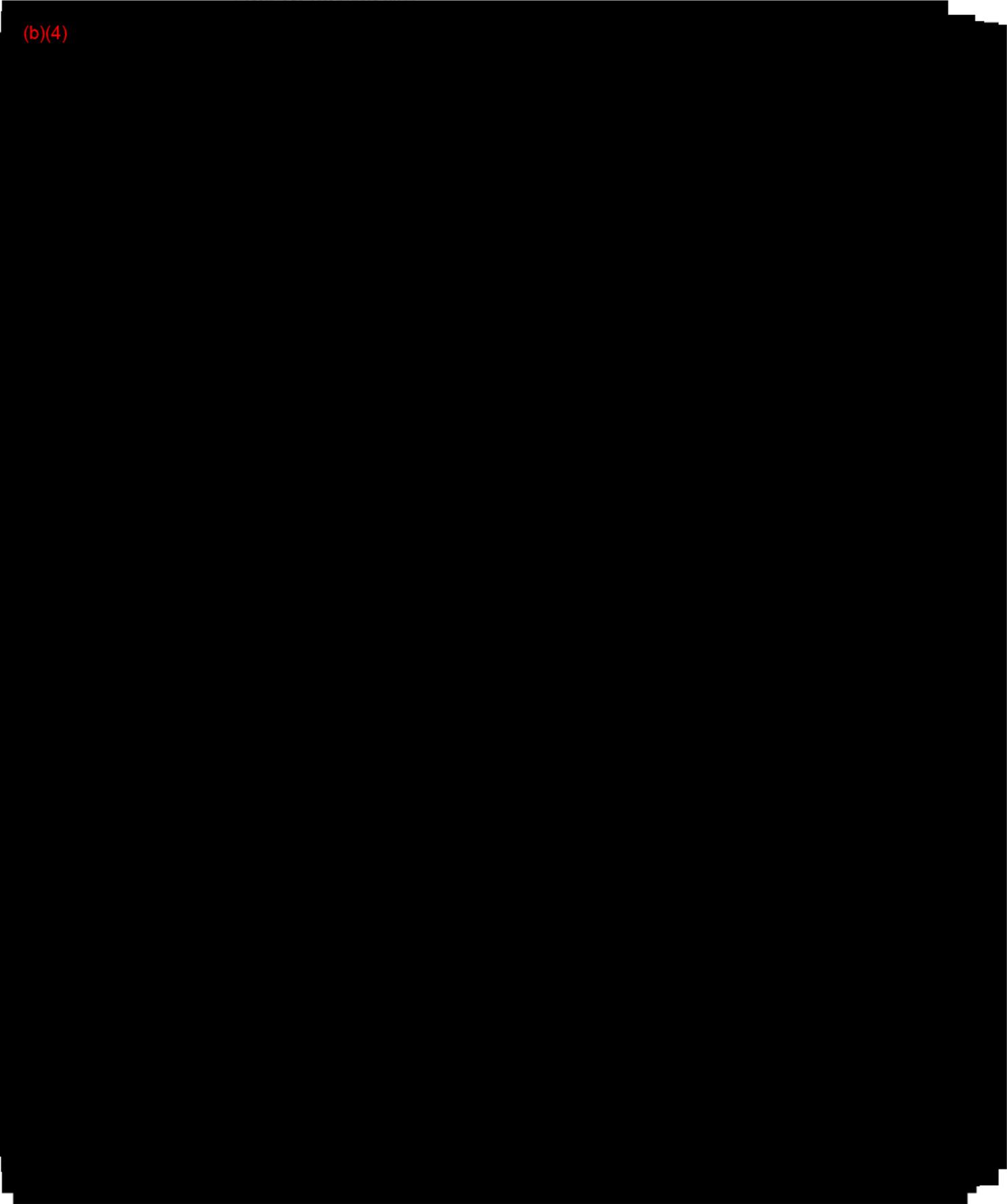
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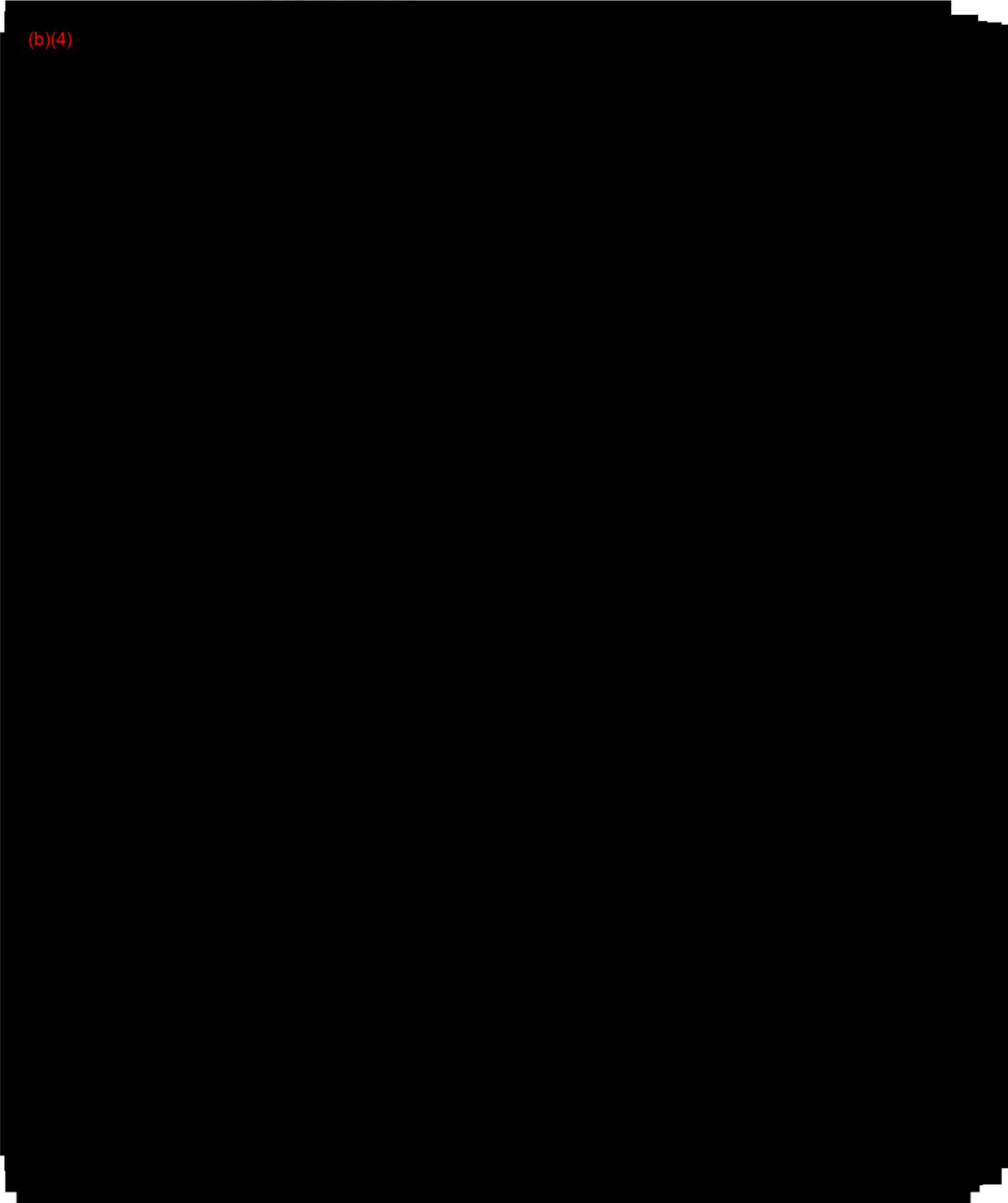
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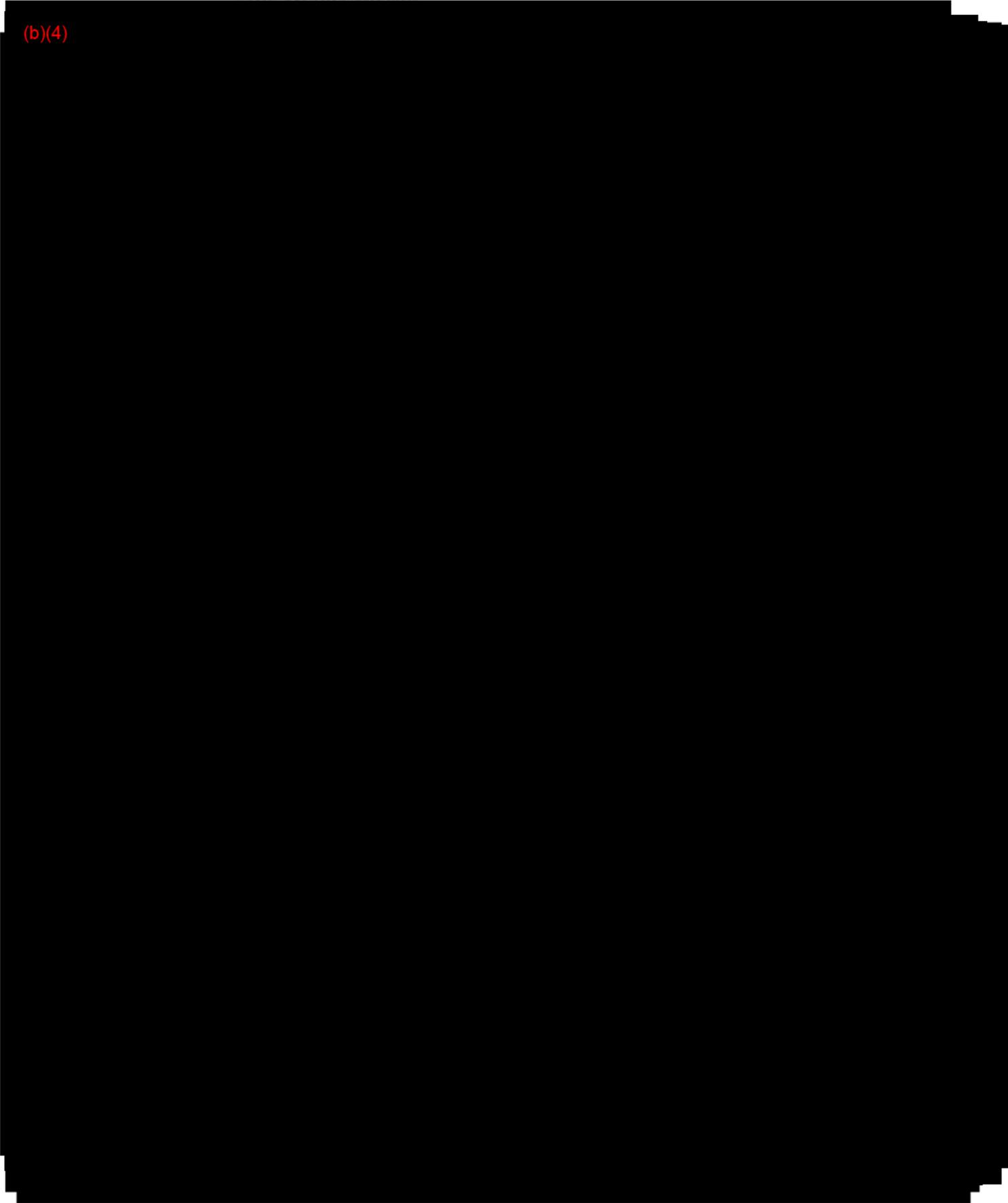
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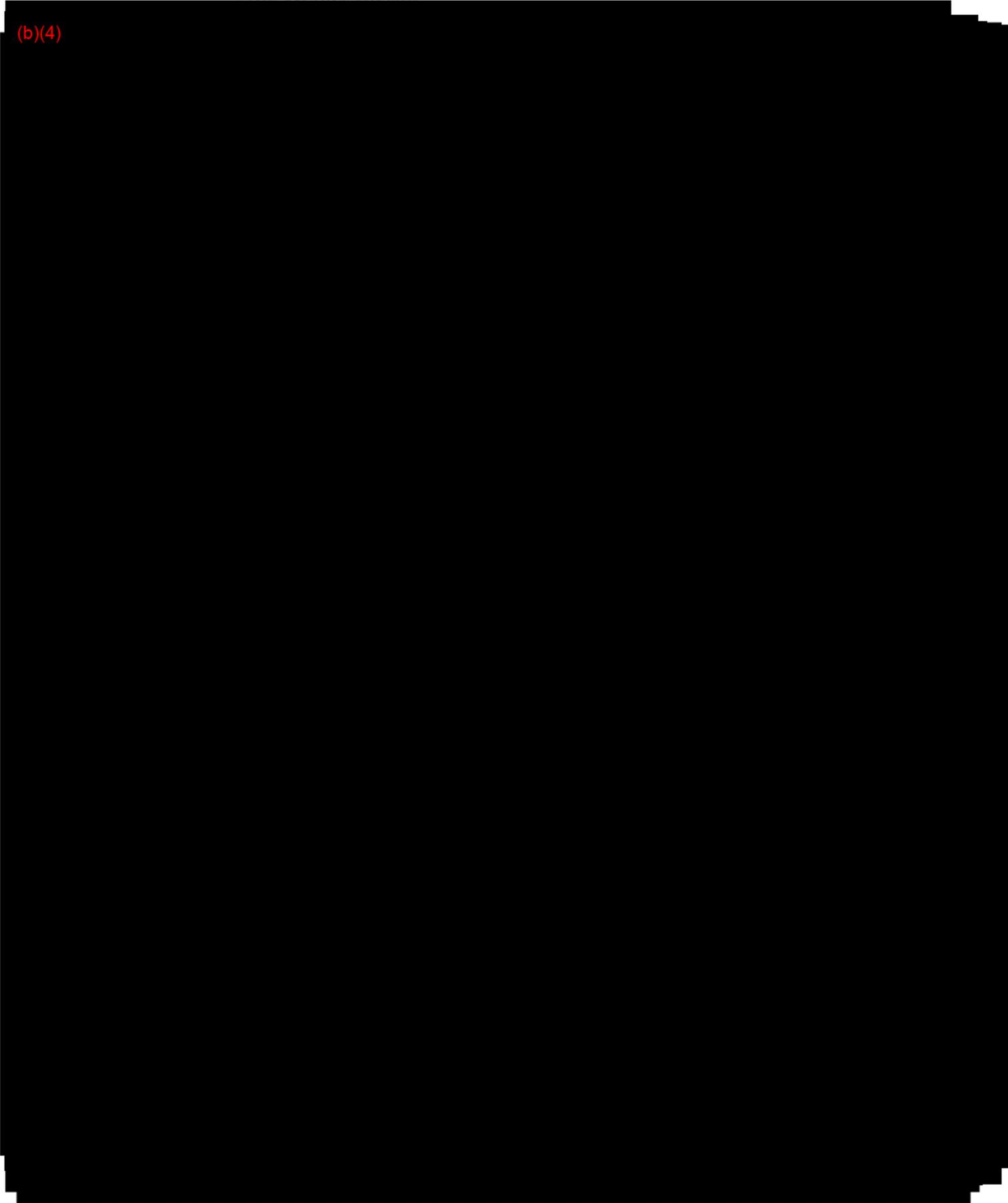
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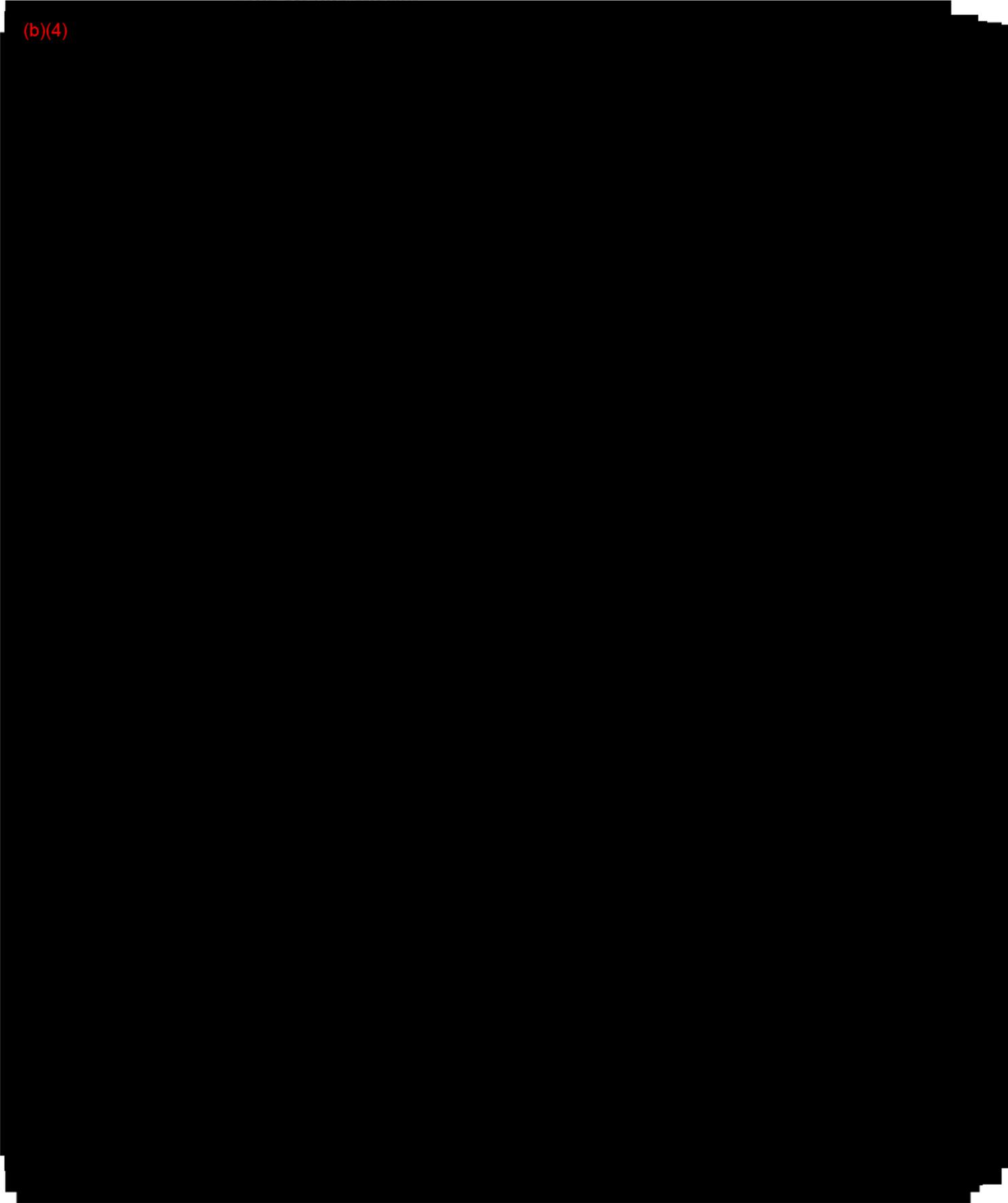
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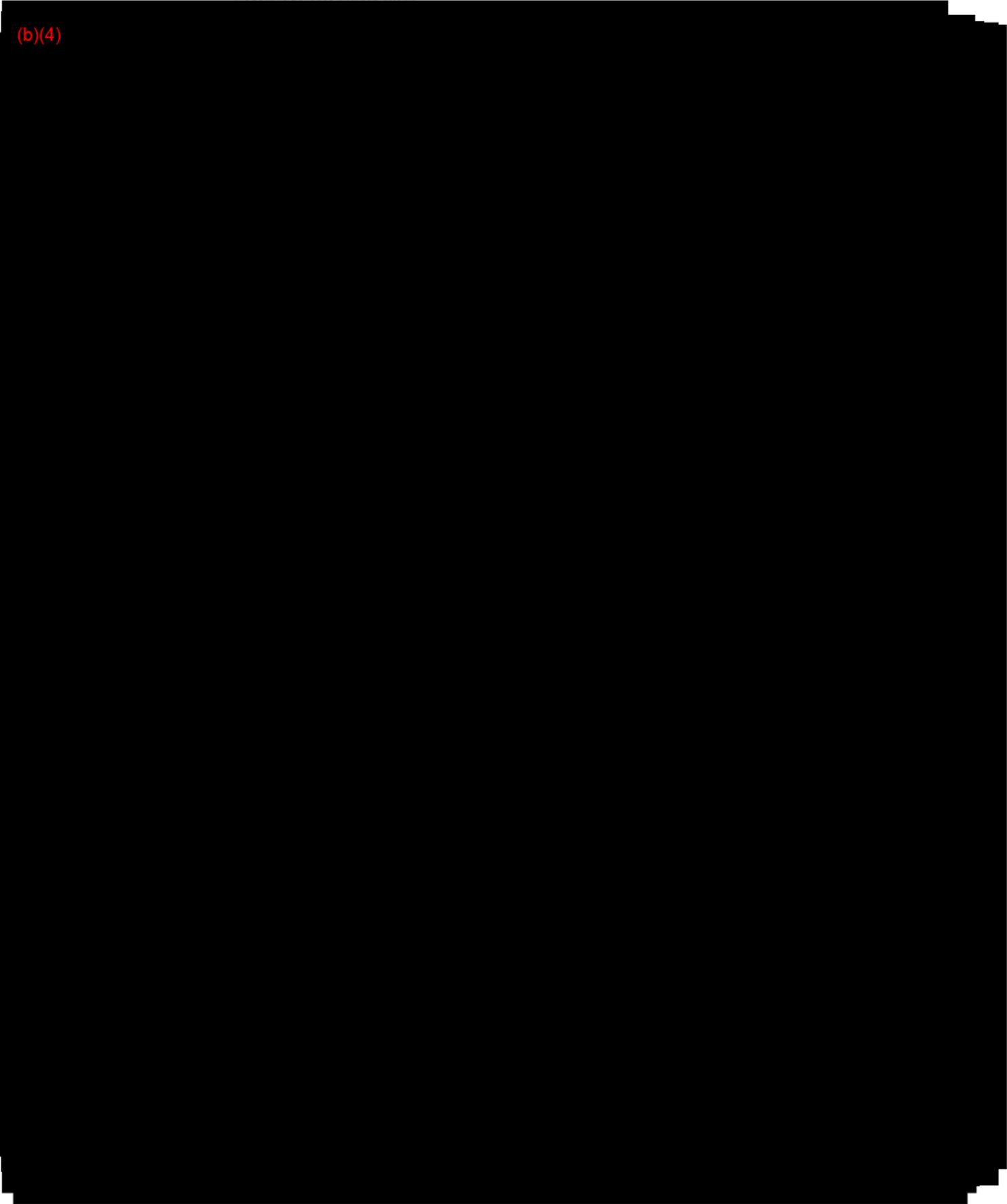
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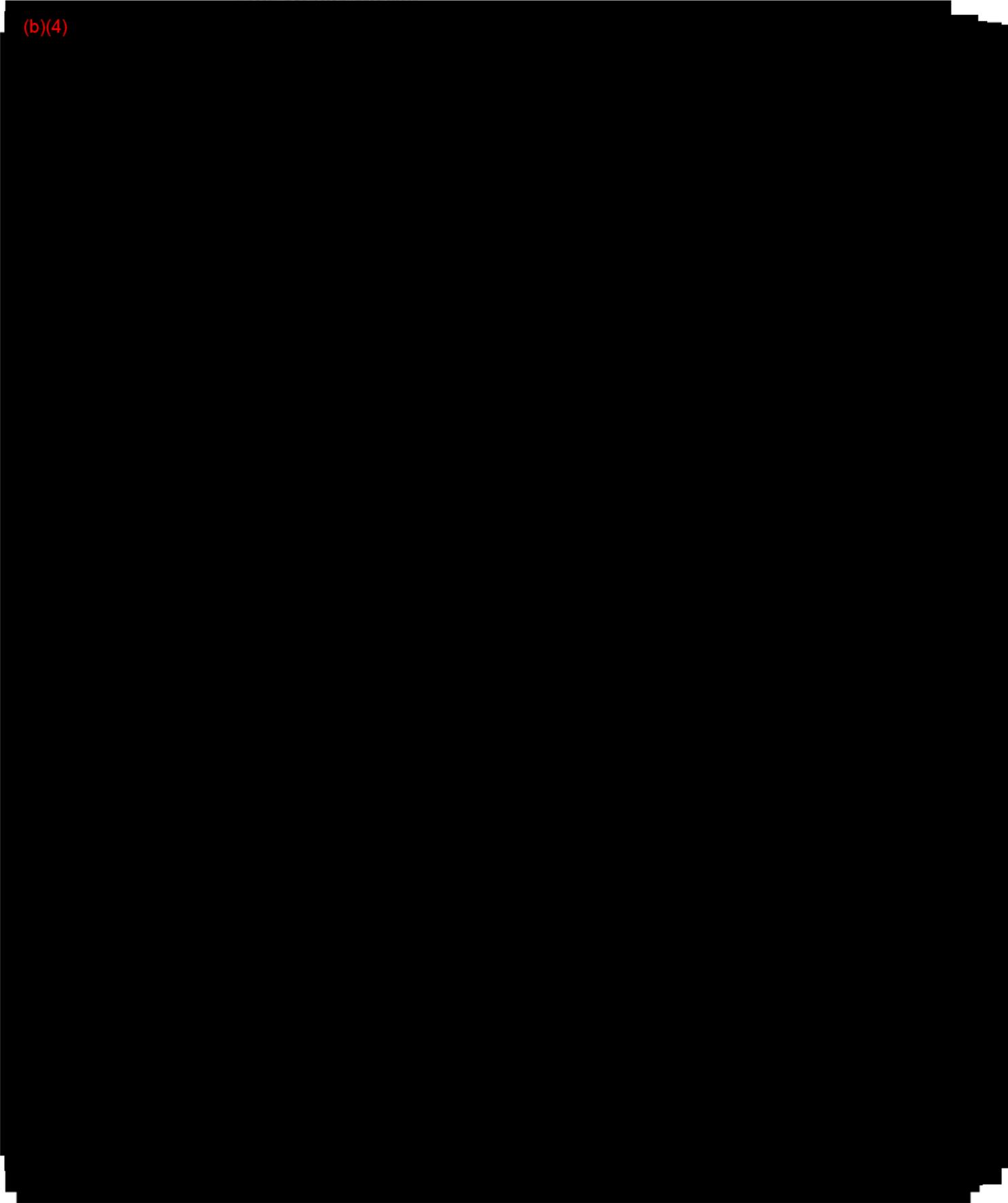
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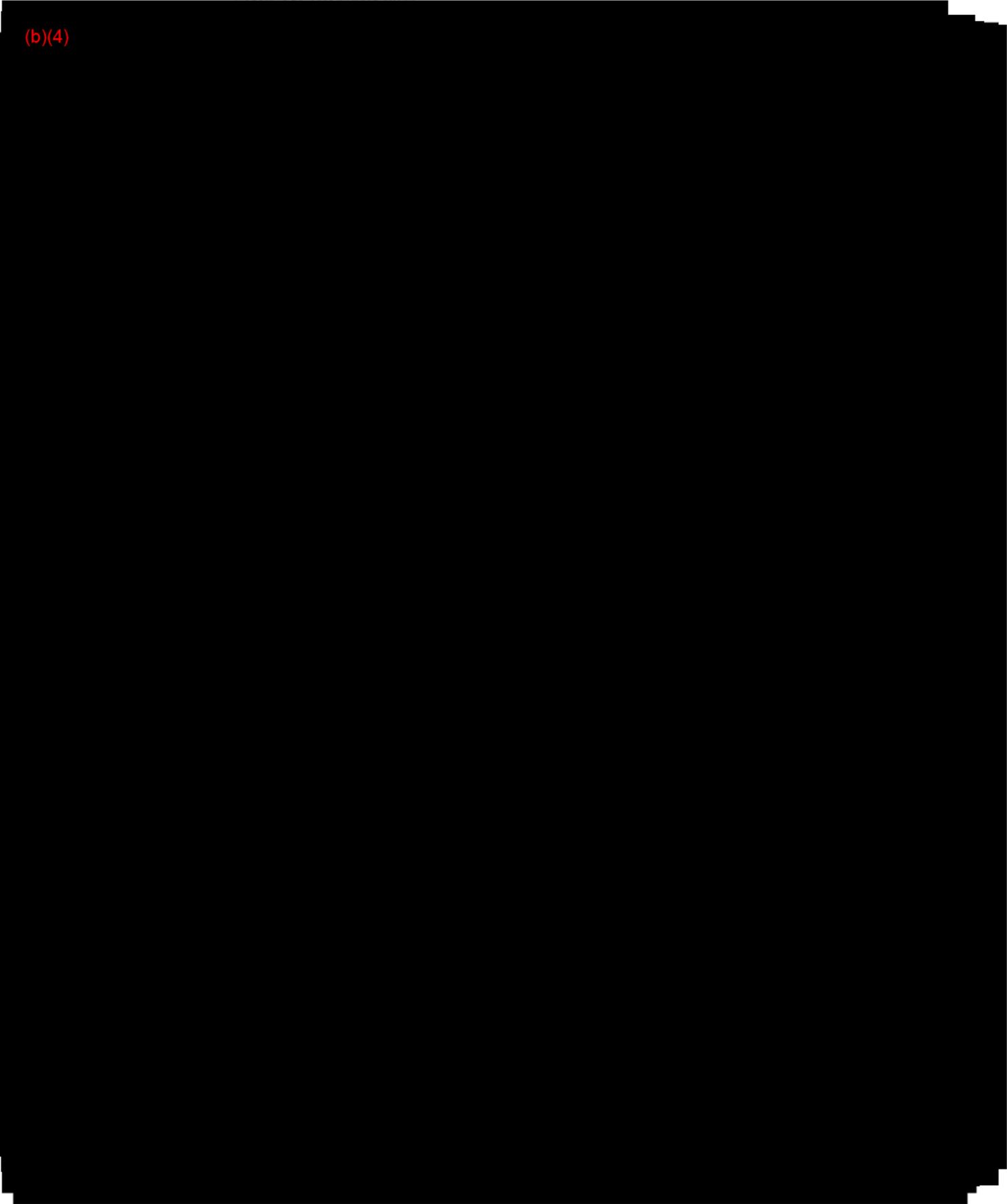
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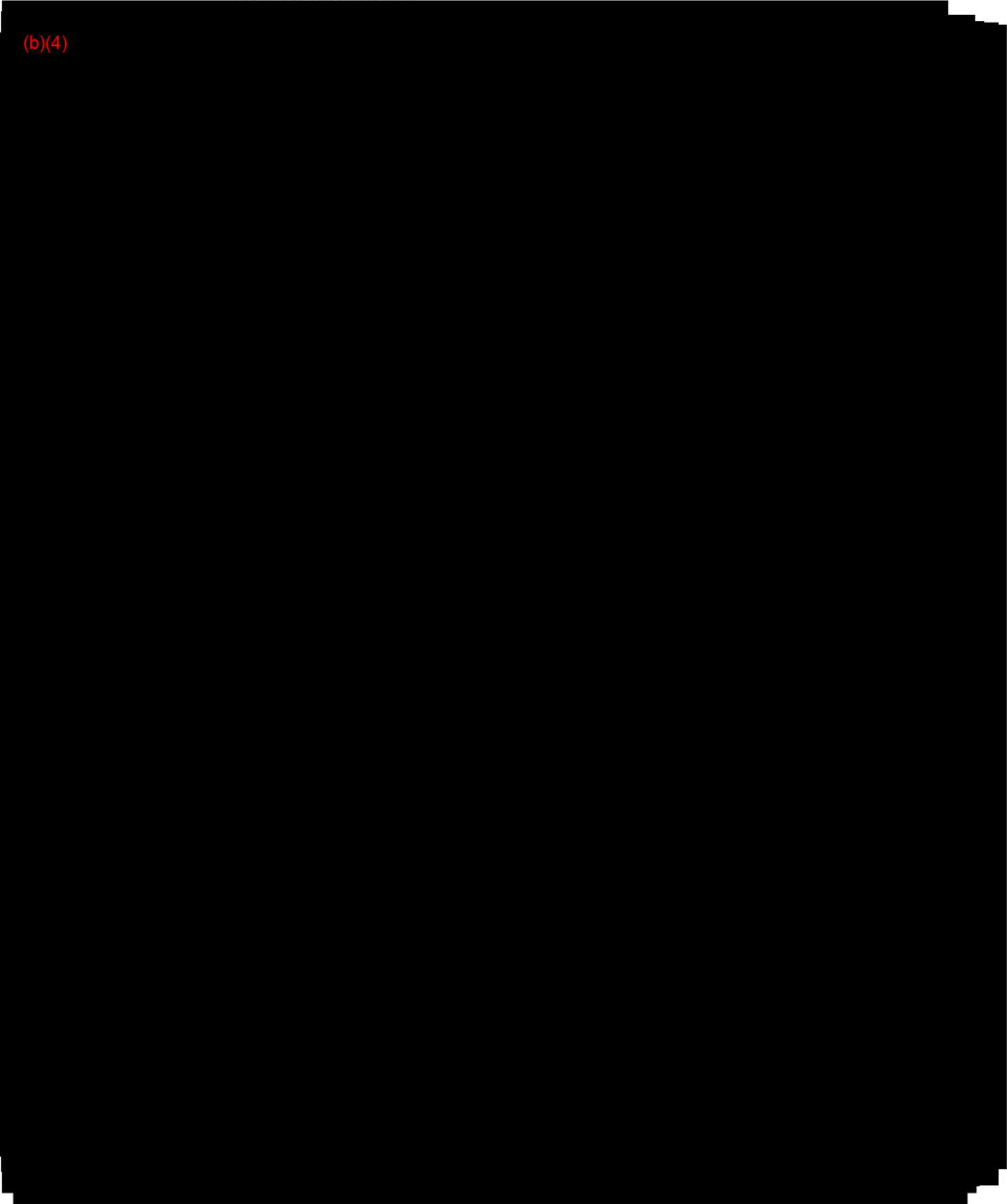
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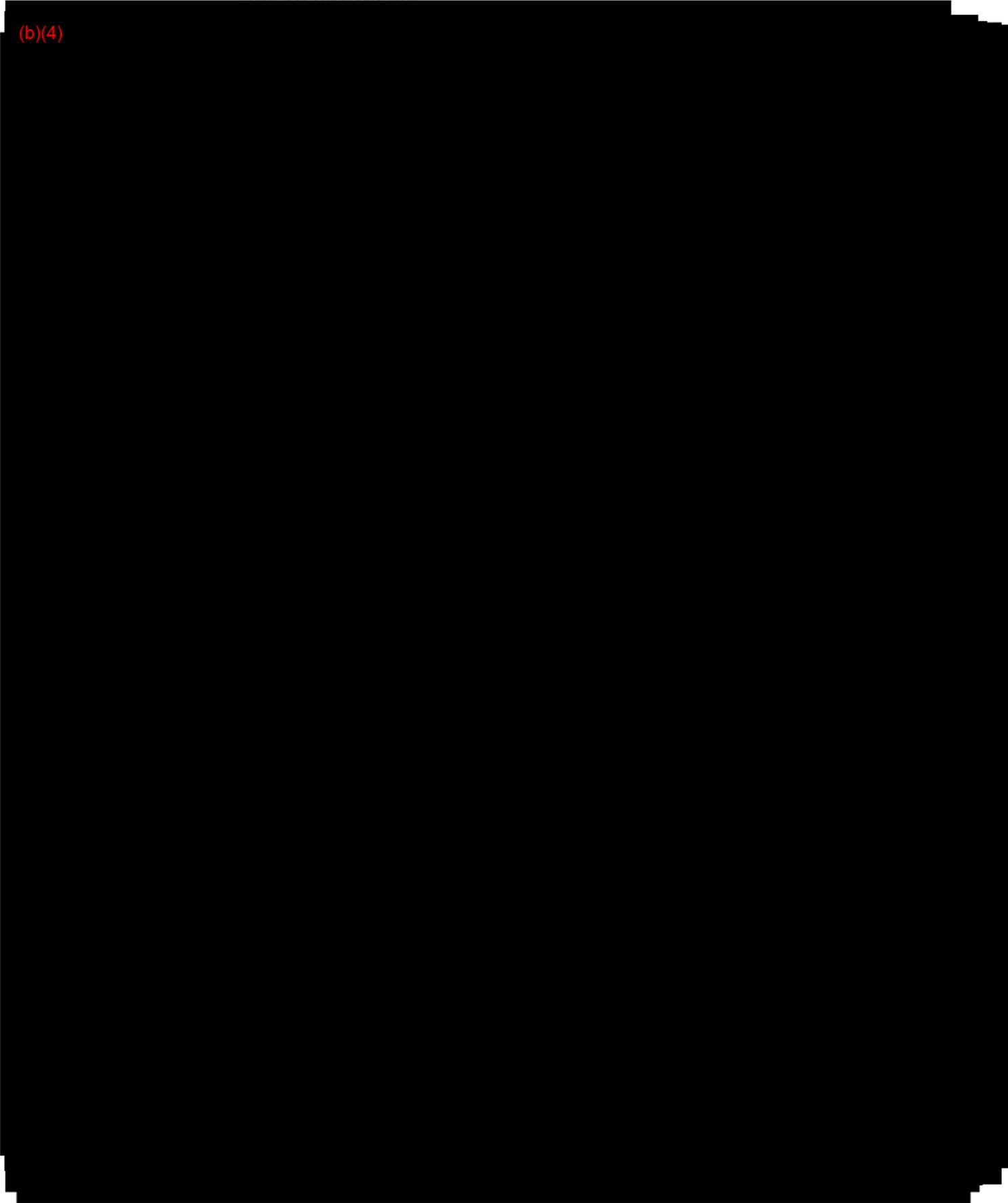
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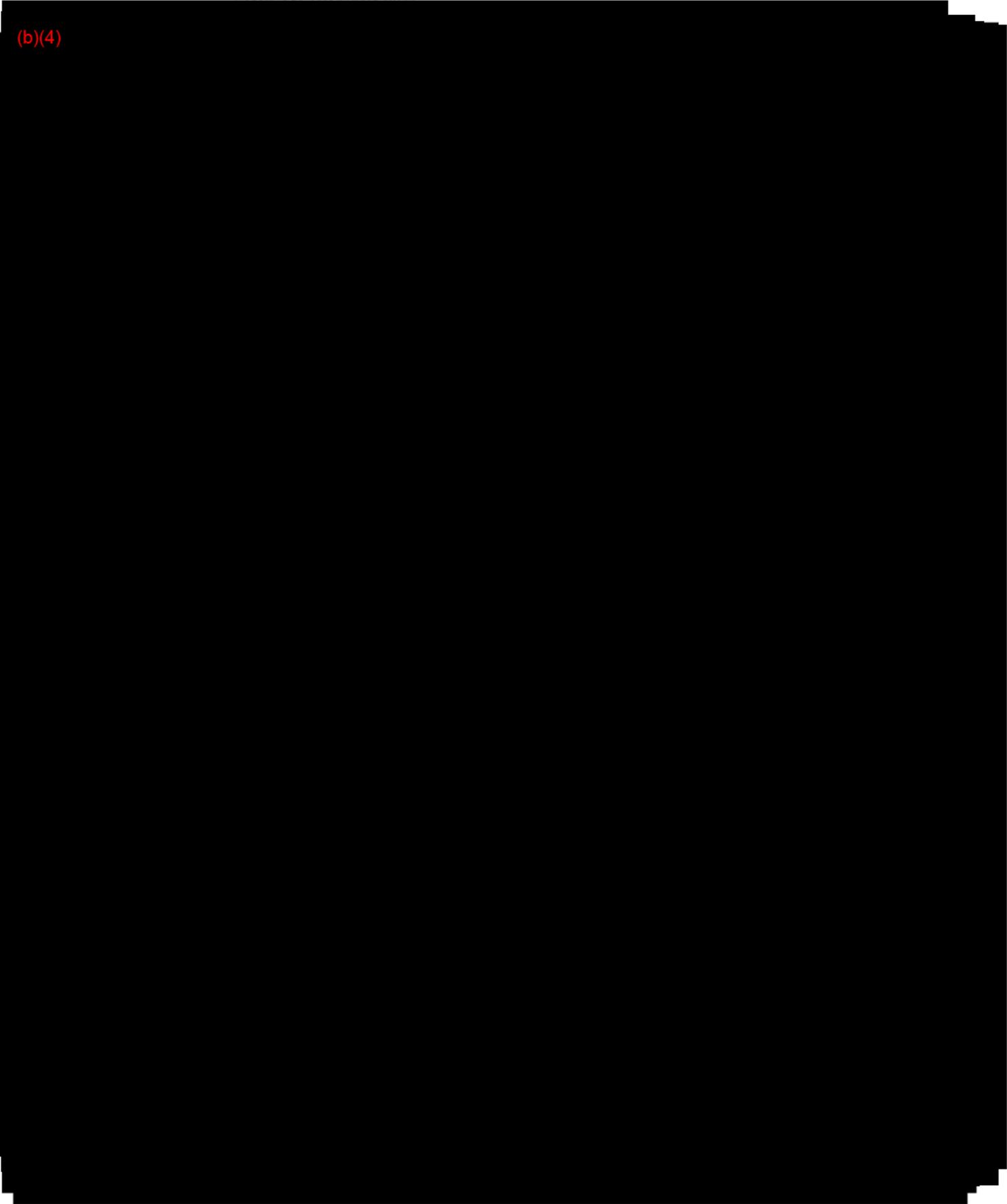
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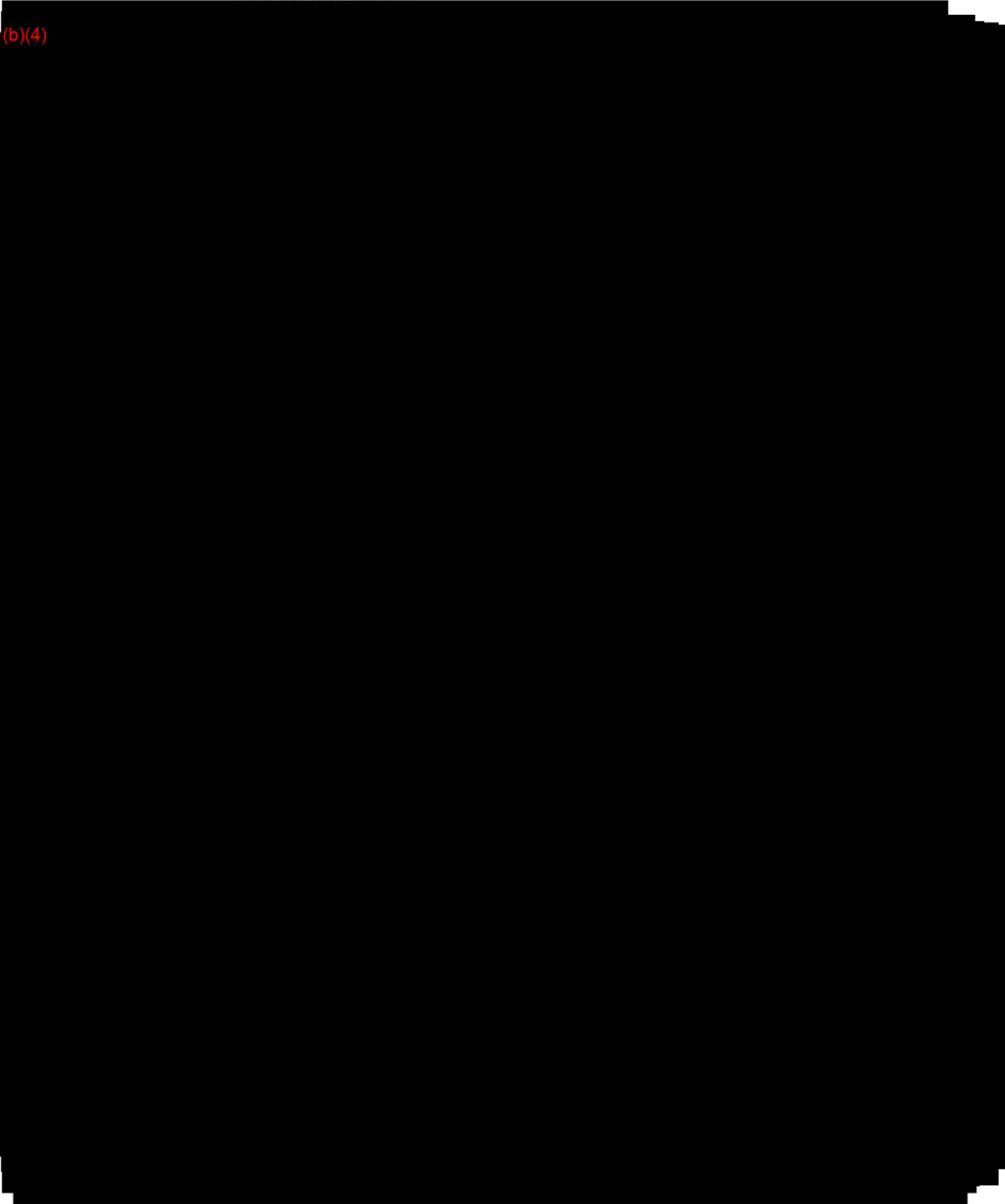
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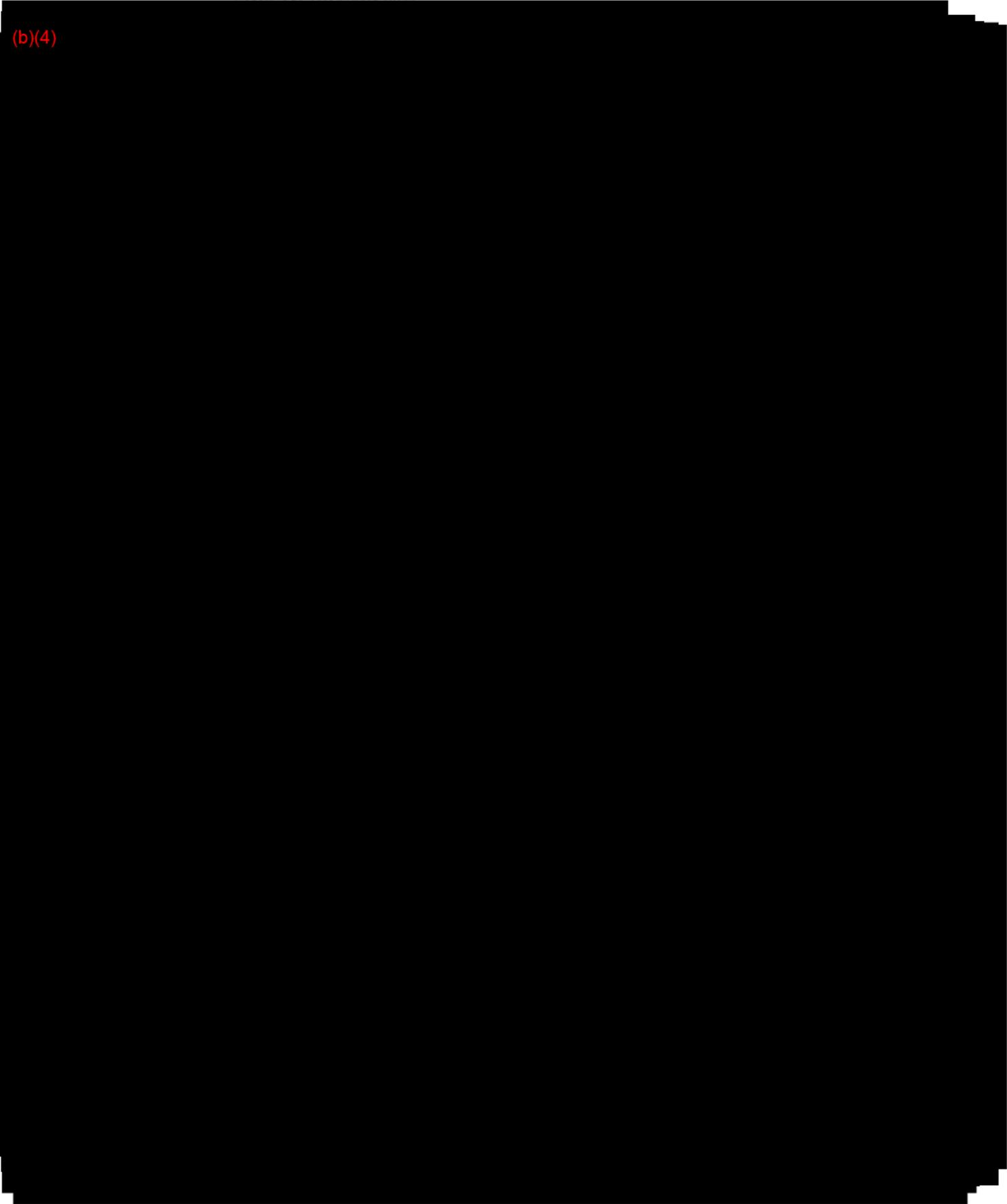
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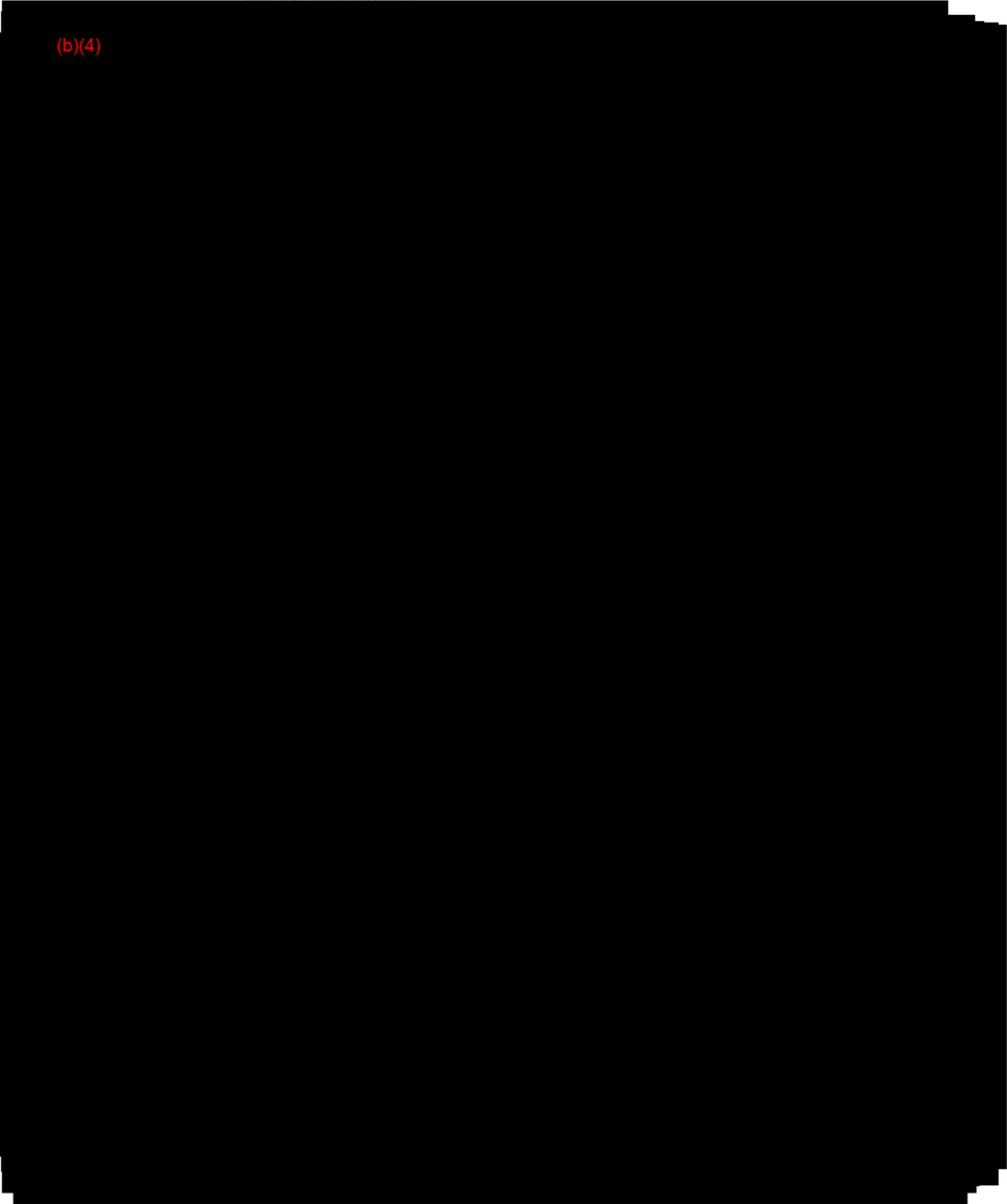
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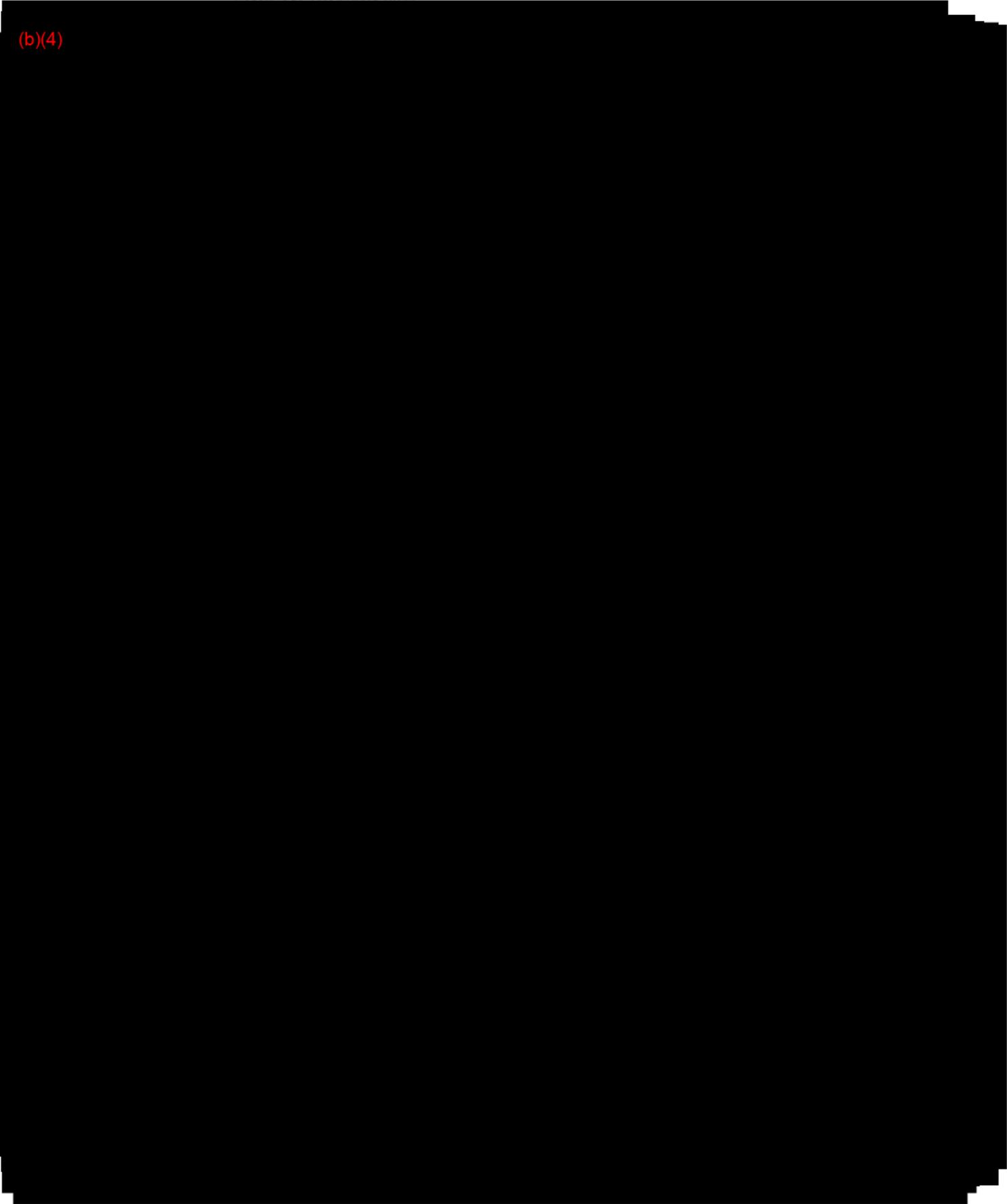
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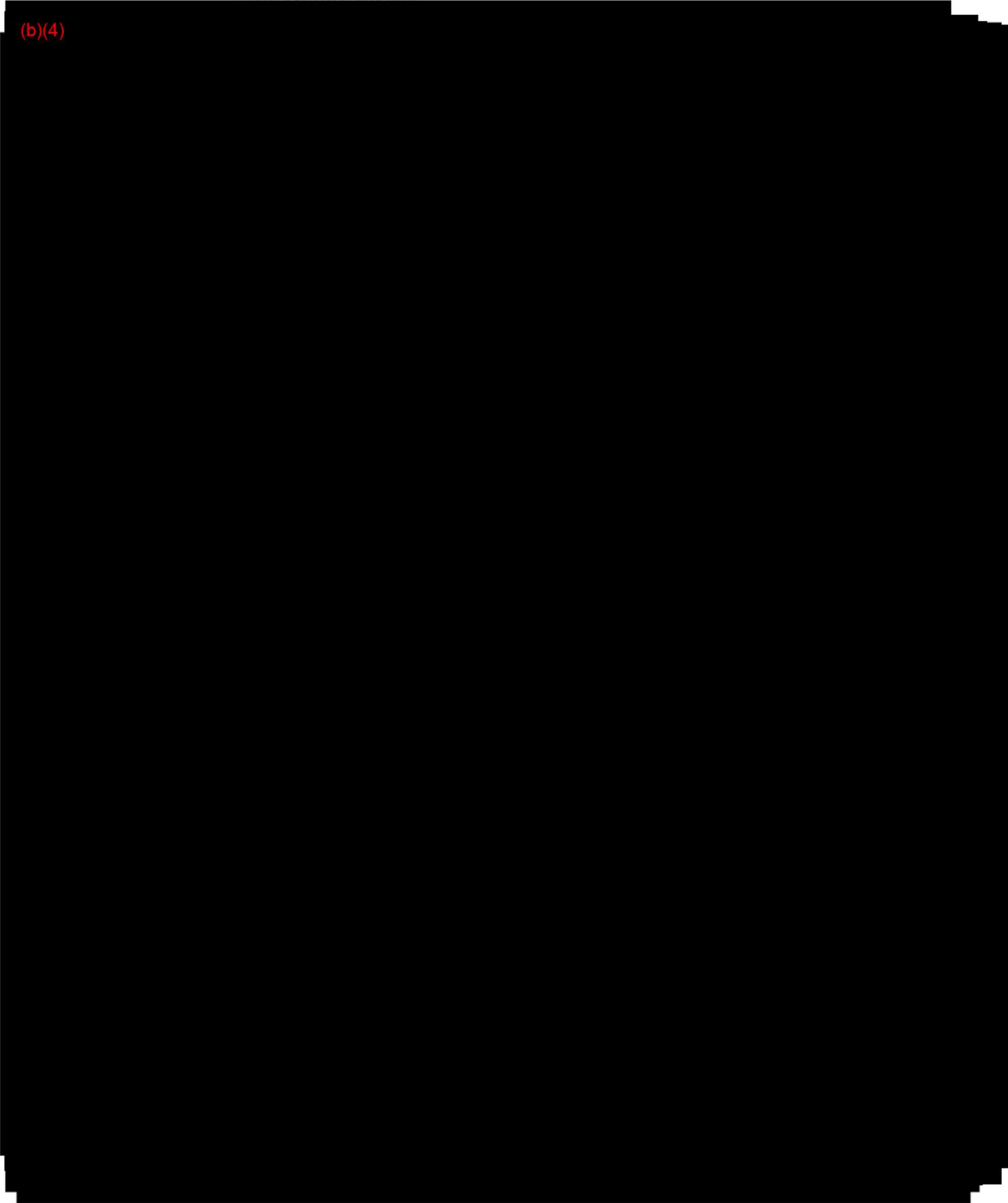
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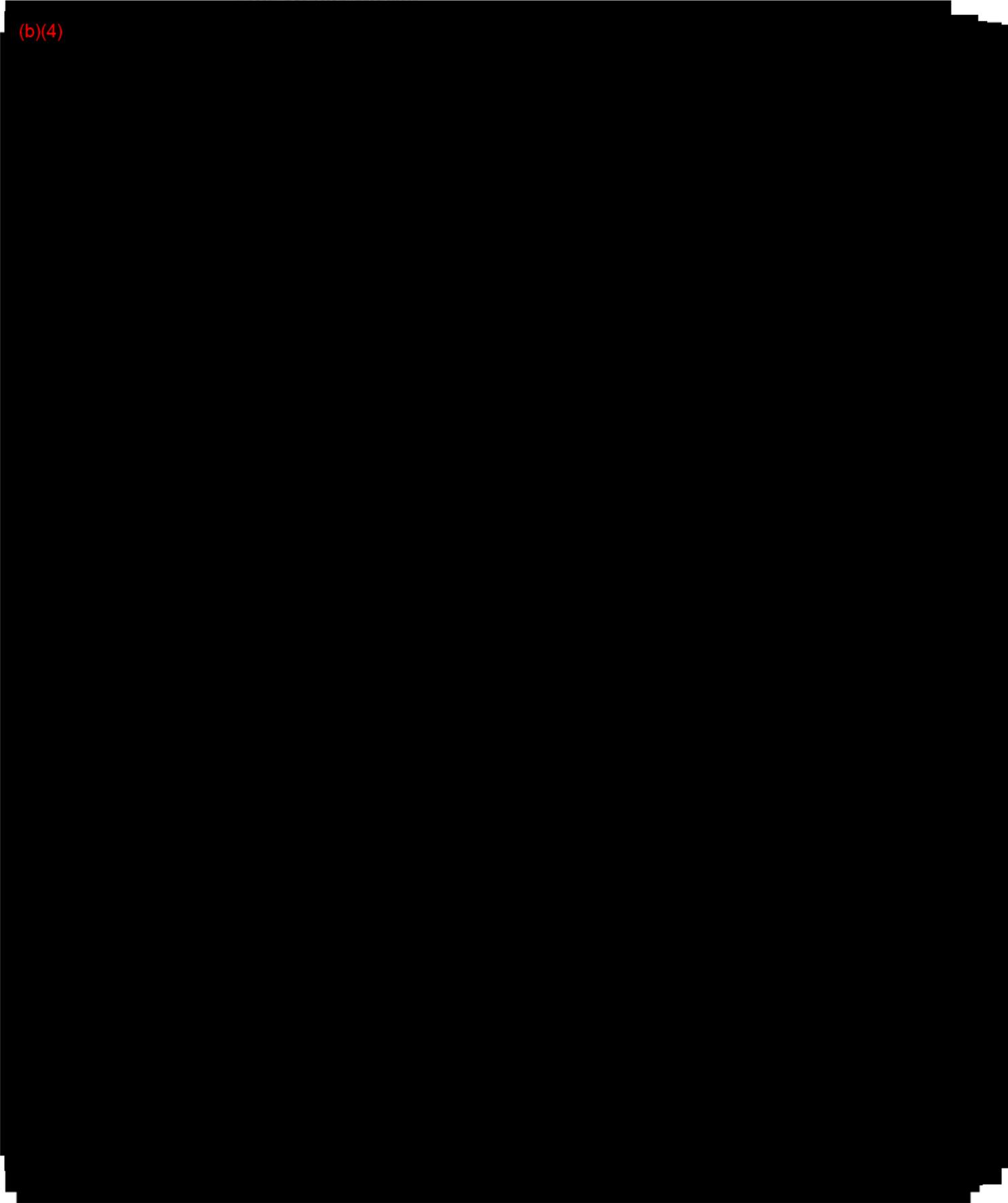
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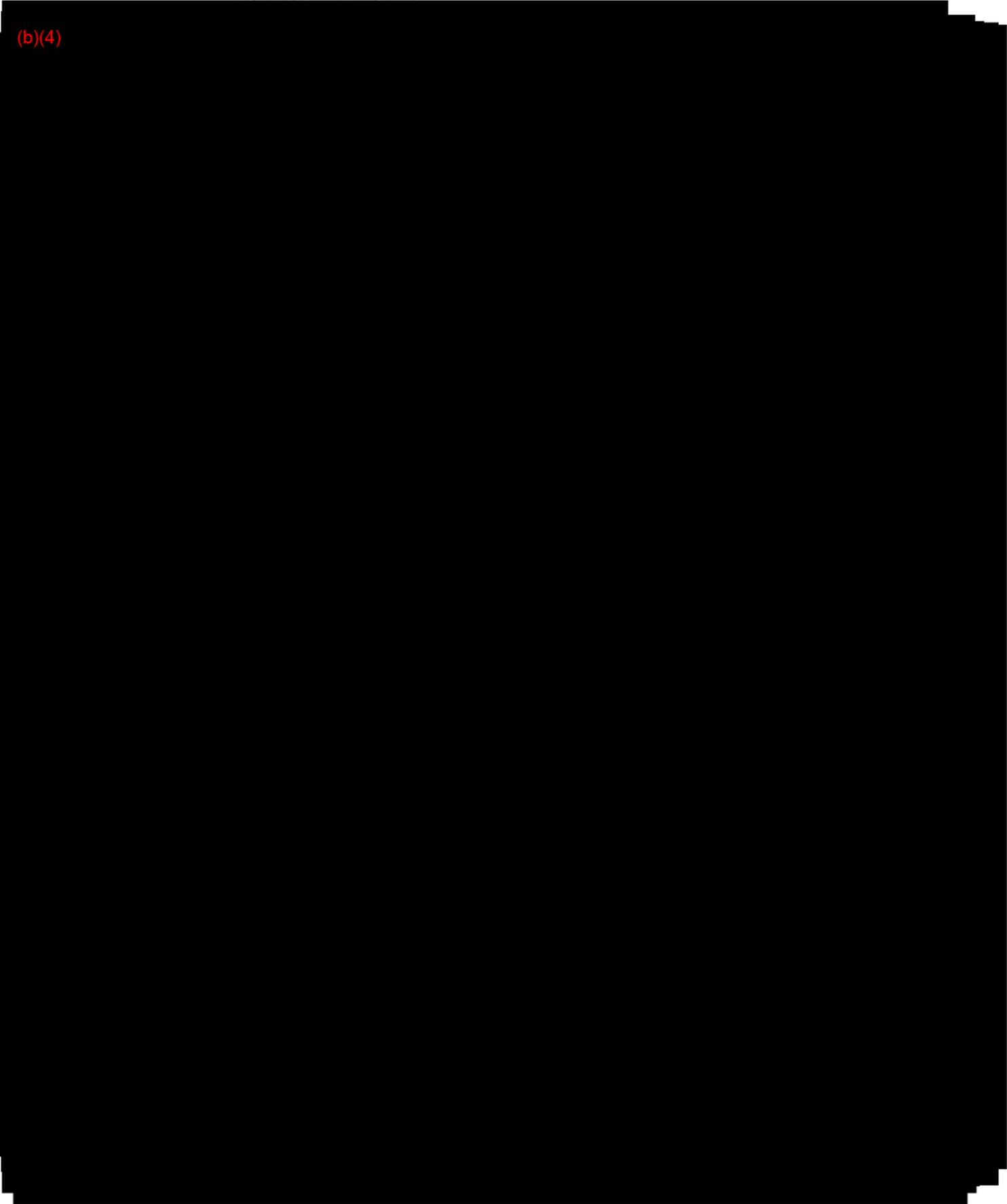
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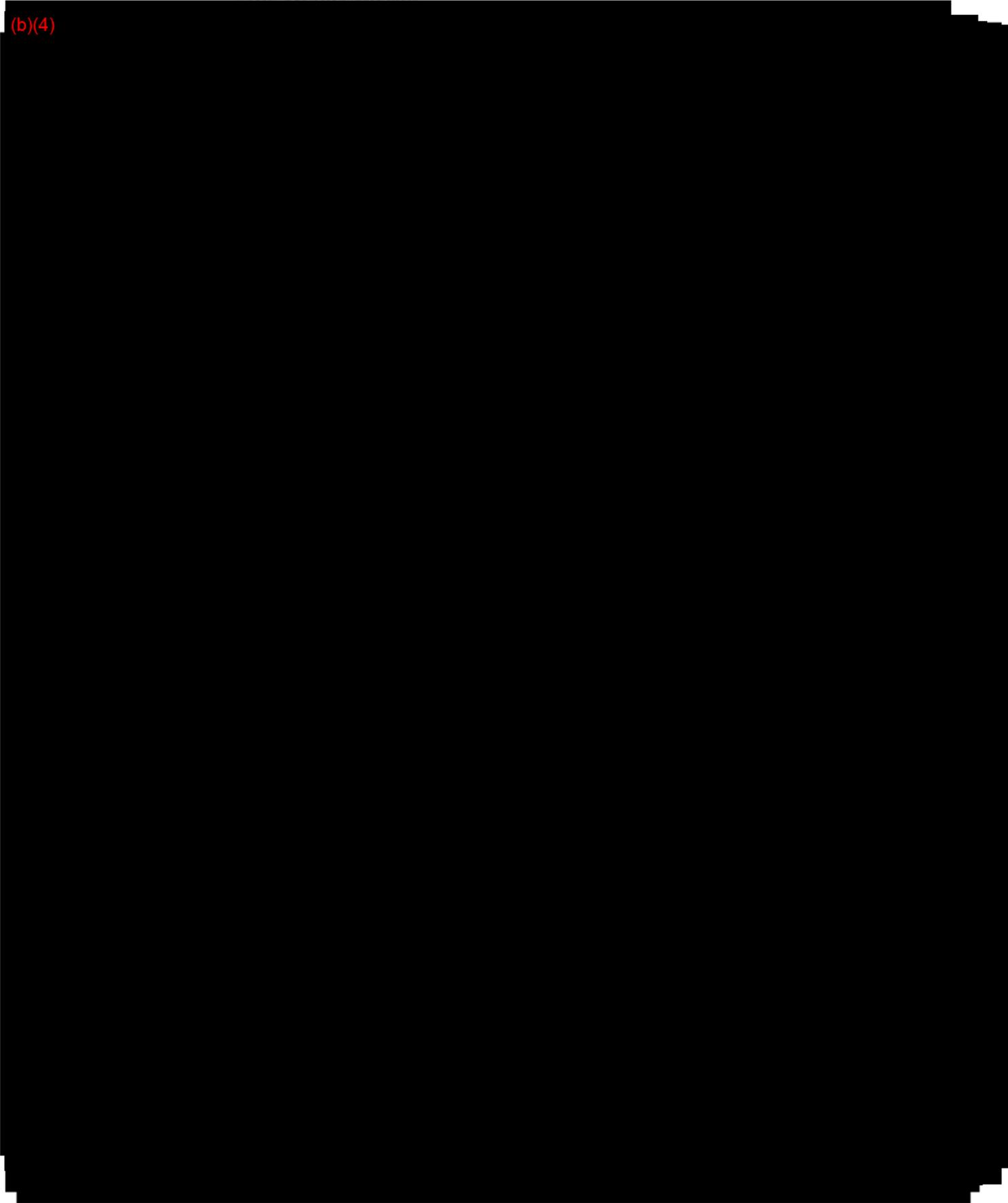
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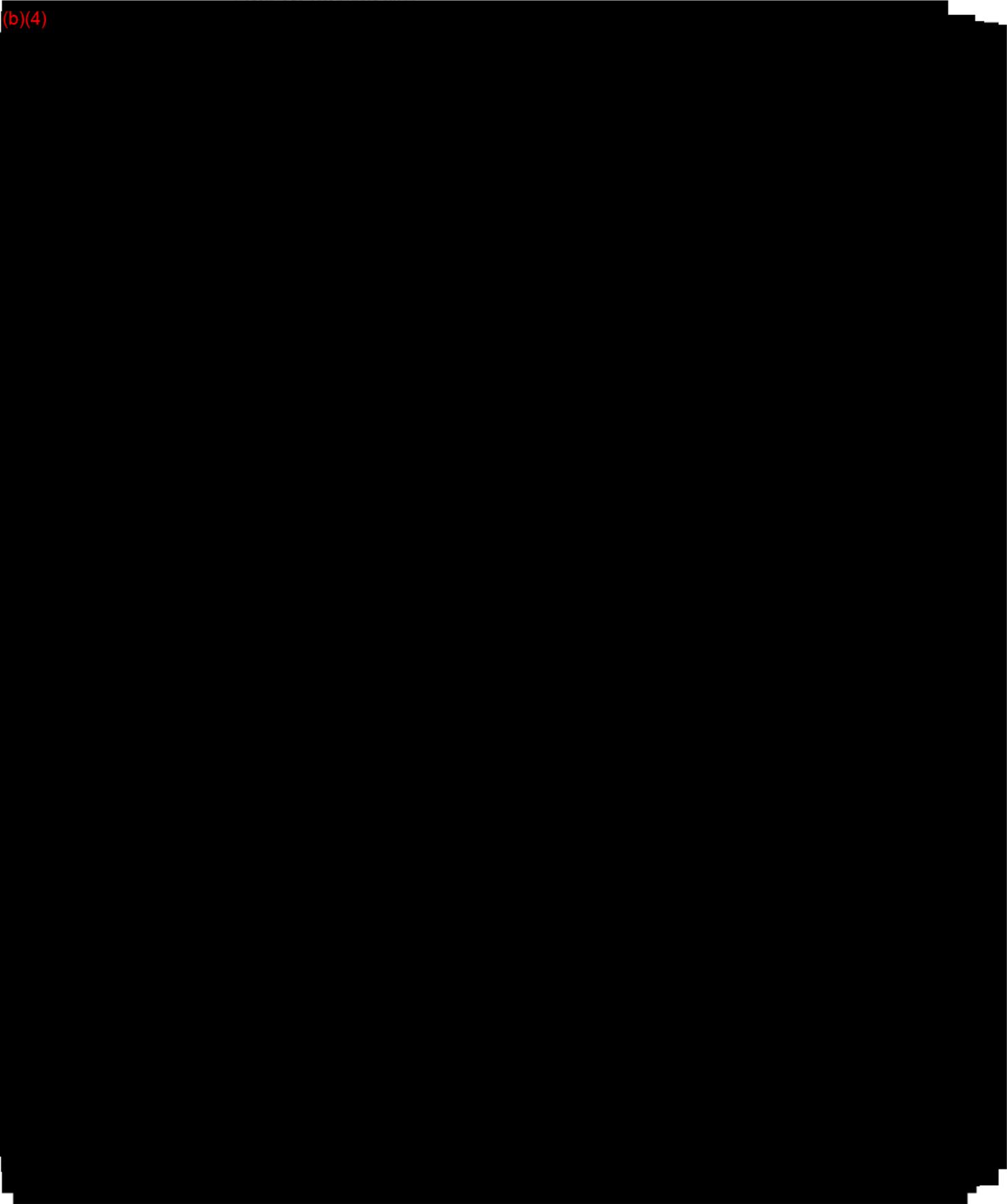
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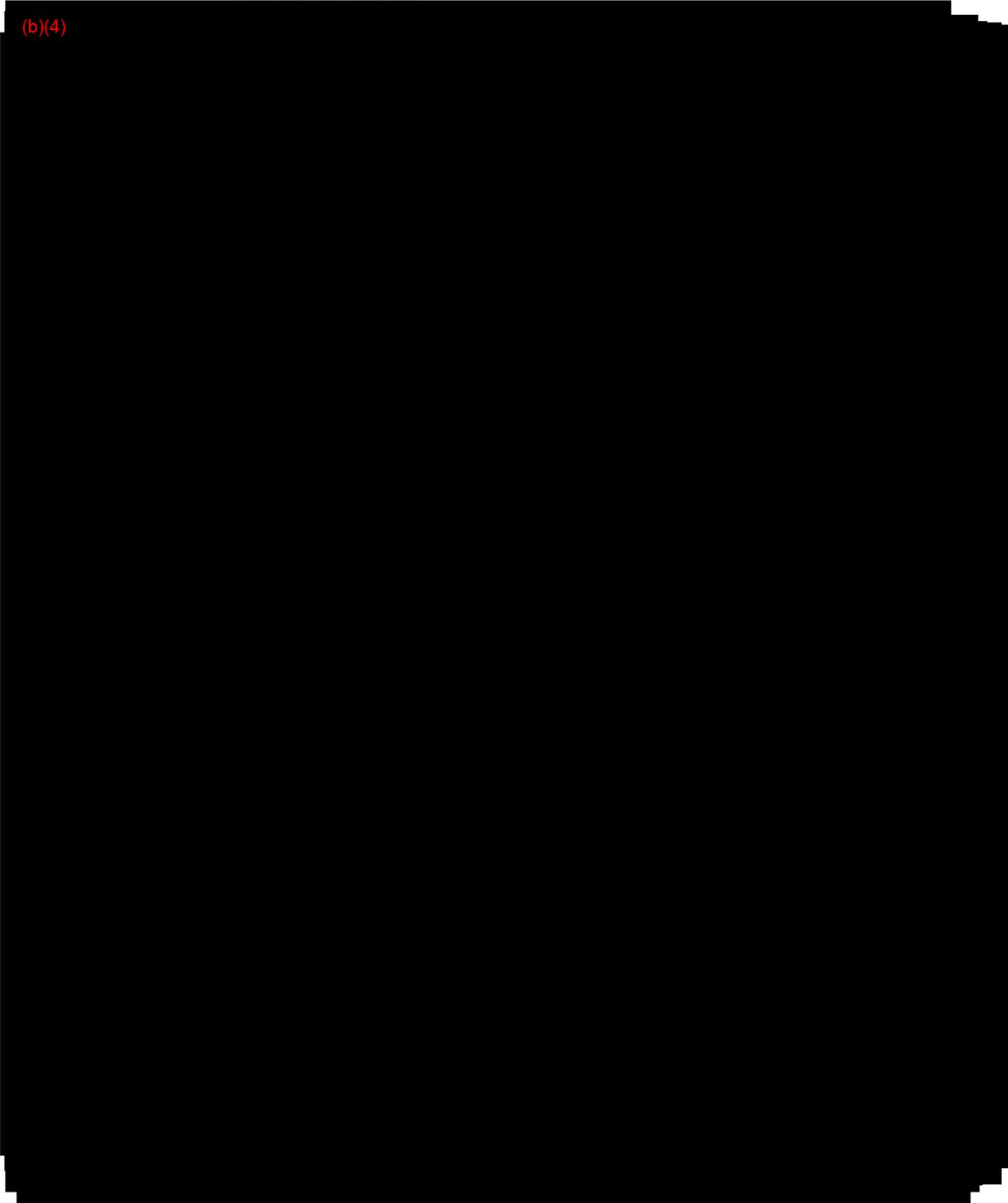
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MORE CONTROL. LESS RISK.

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(b)(4) Software Information

Confidential Proprietary Information

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ST. JUDE MEDICAL

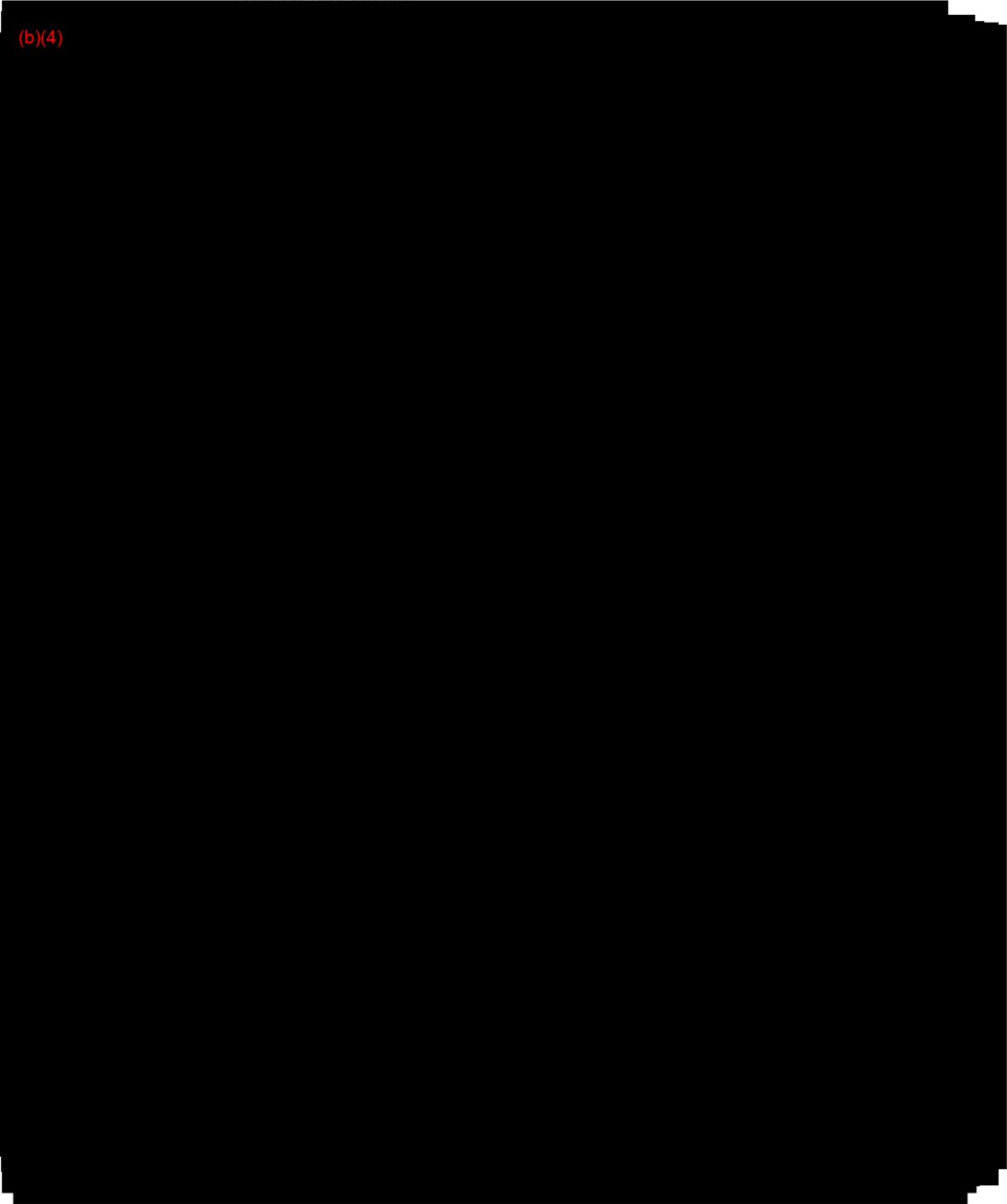
MORE CONTROL. LESS RISK.

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ST. JUDE MEDICAL

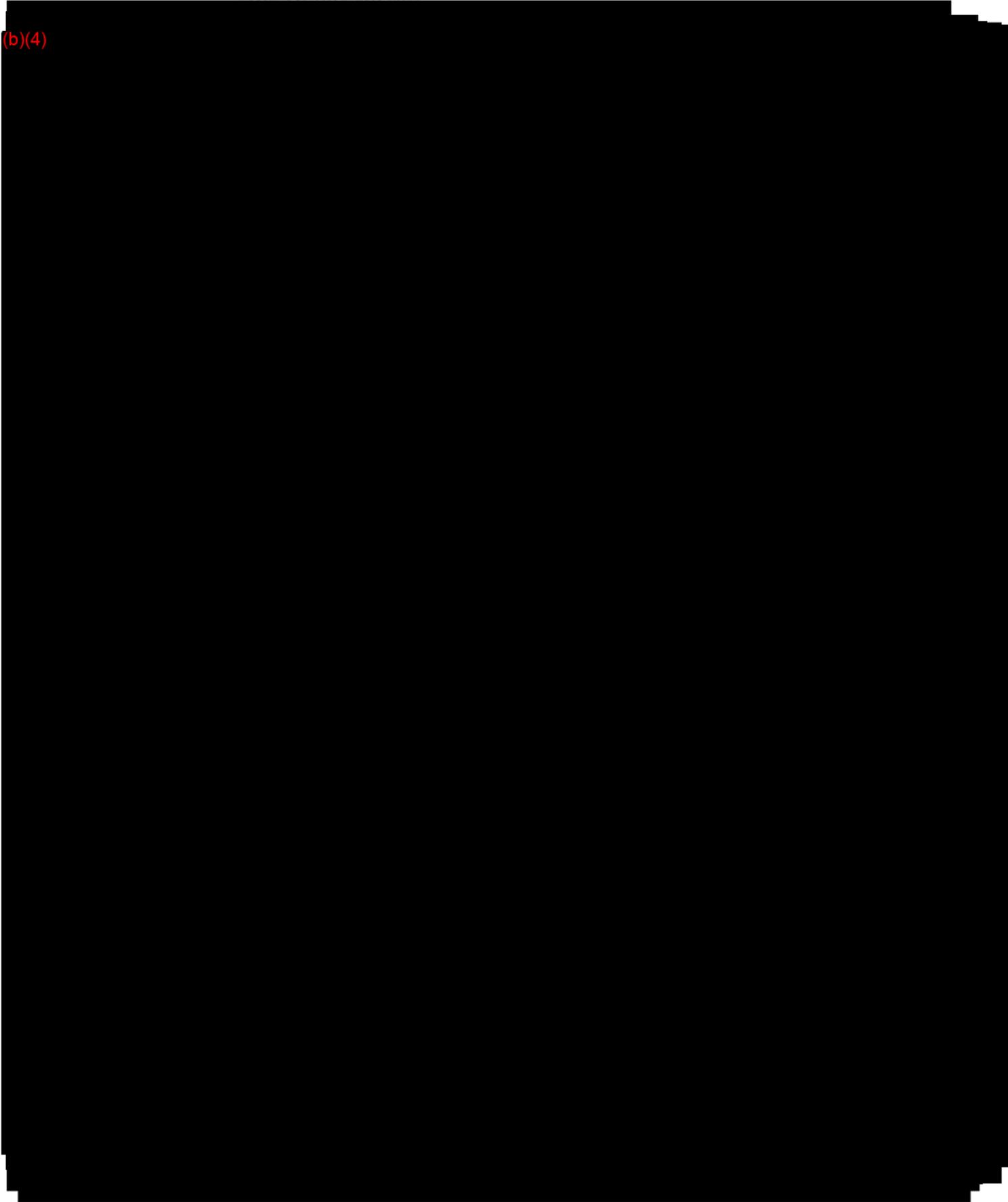
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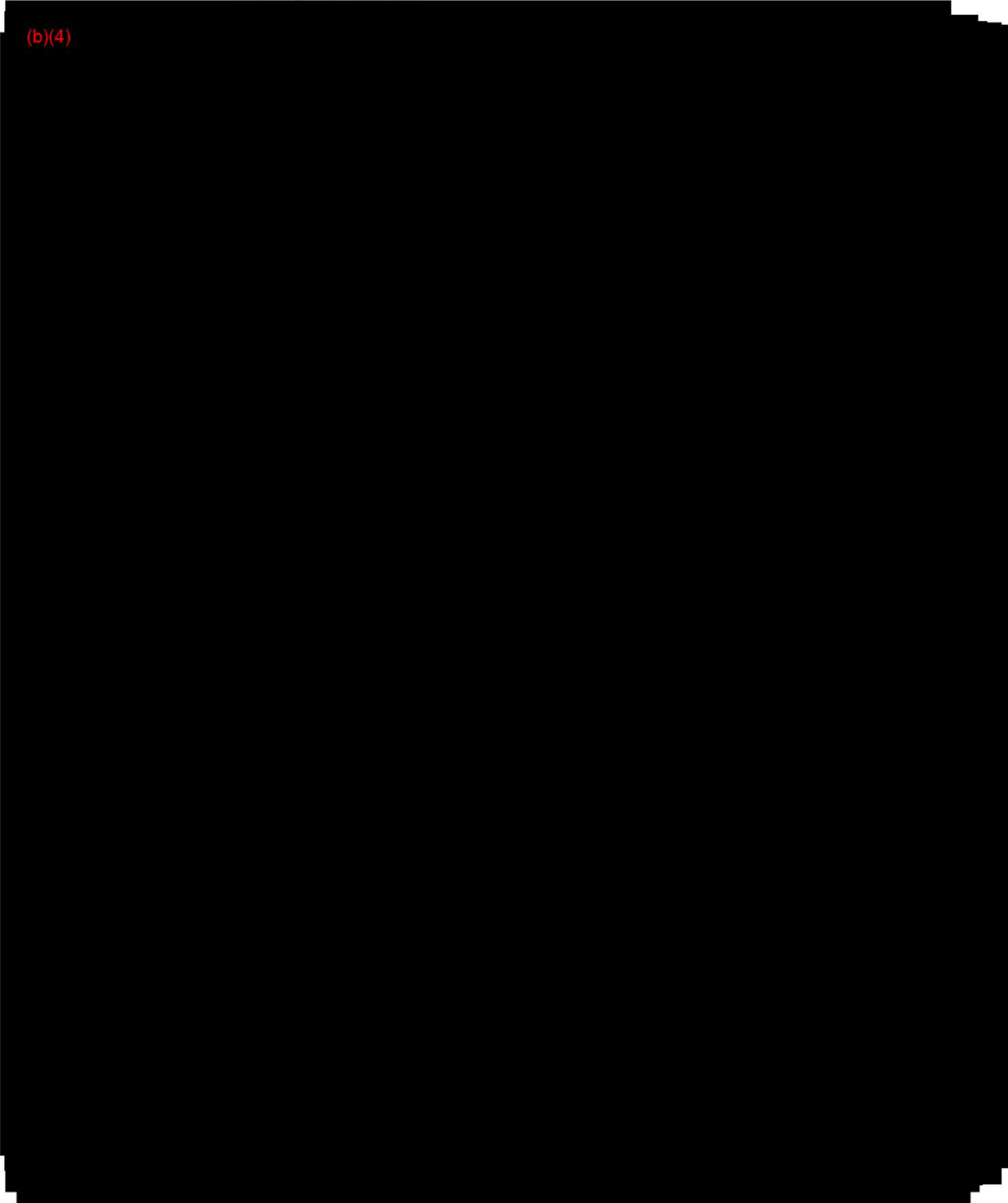
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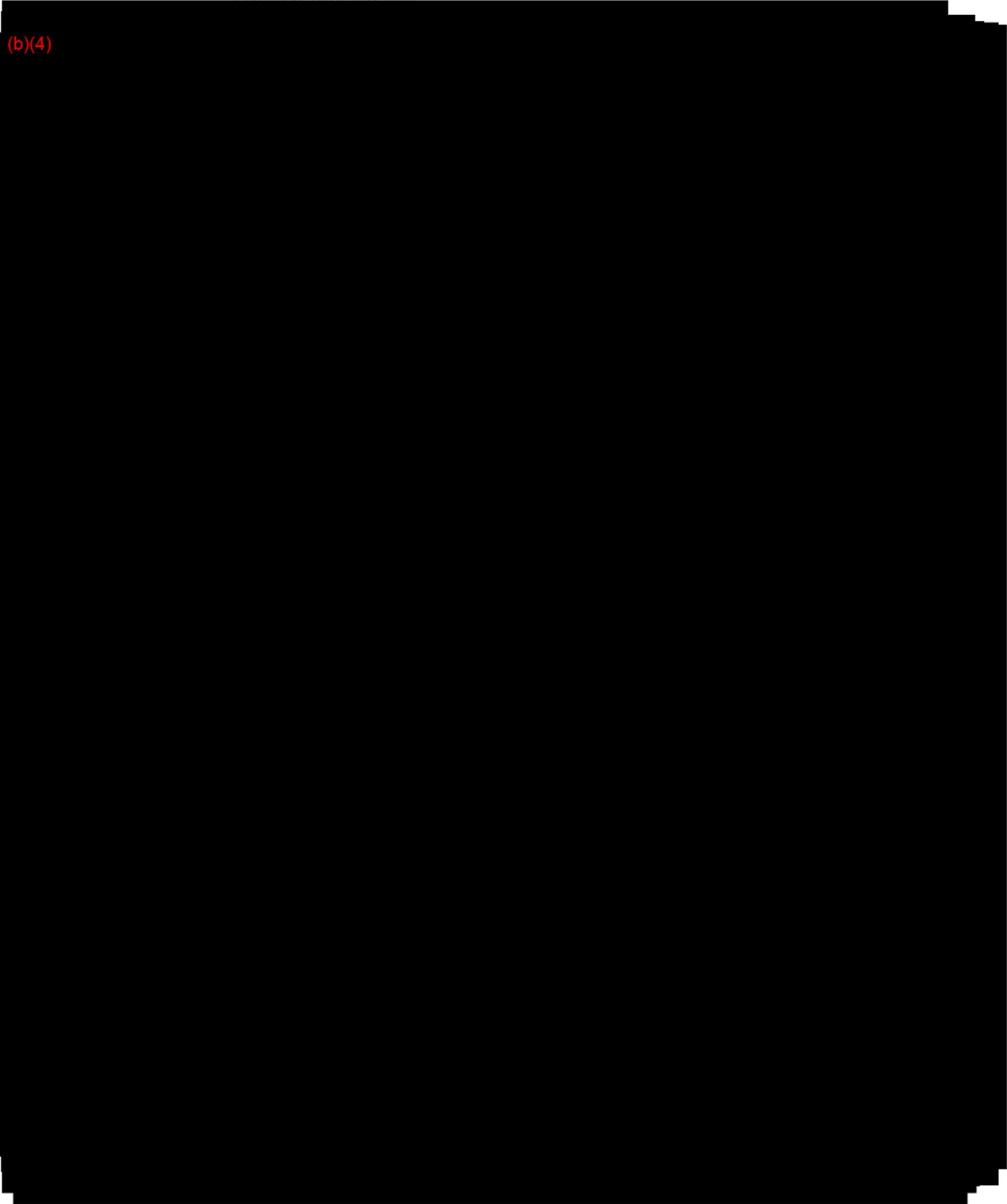
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ATTACHMENT 8-5

Software Test Report (STR) for

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STR

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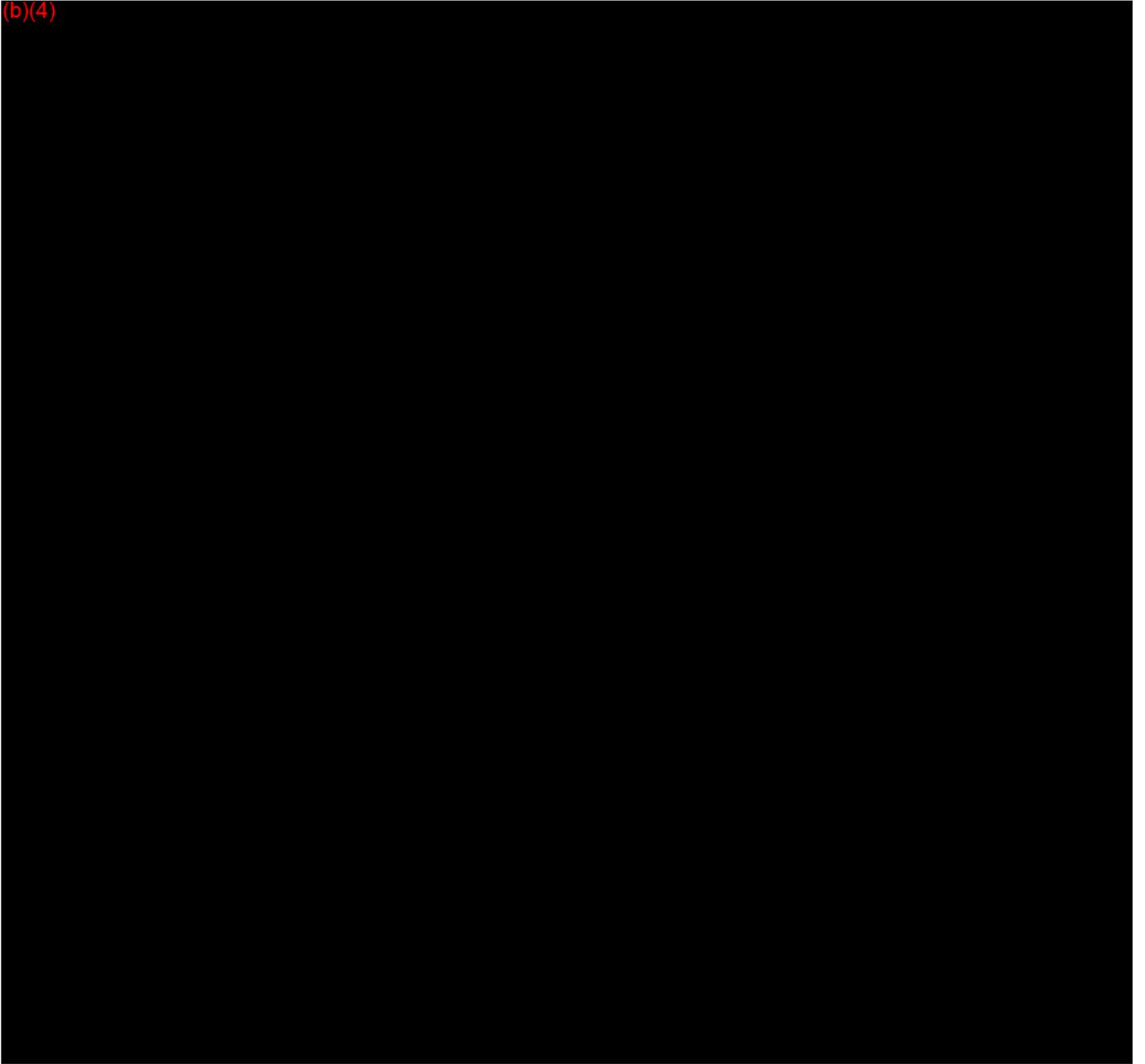


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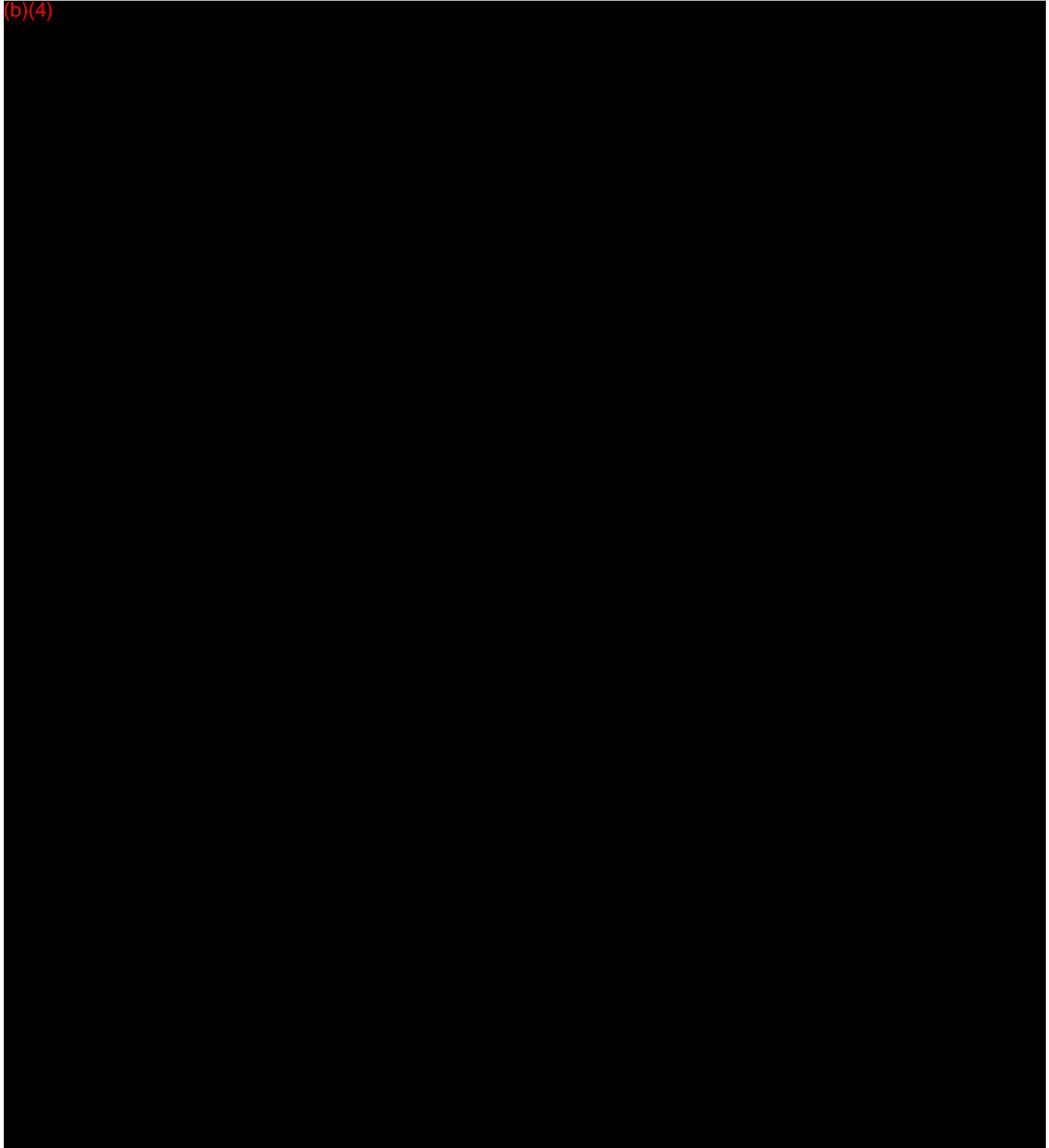
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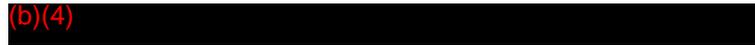
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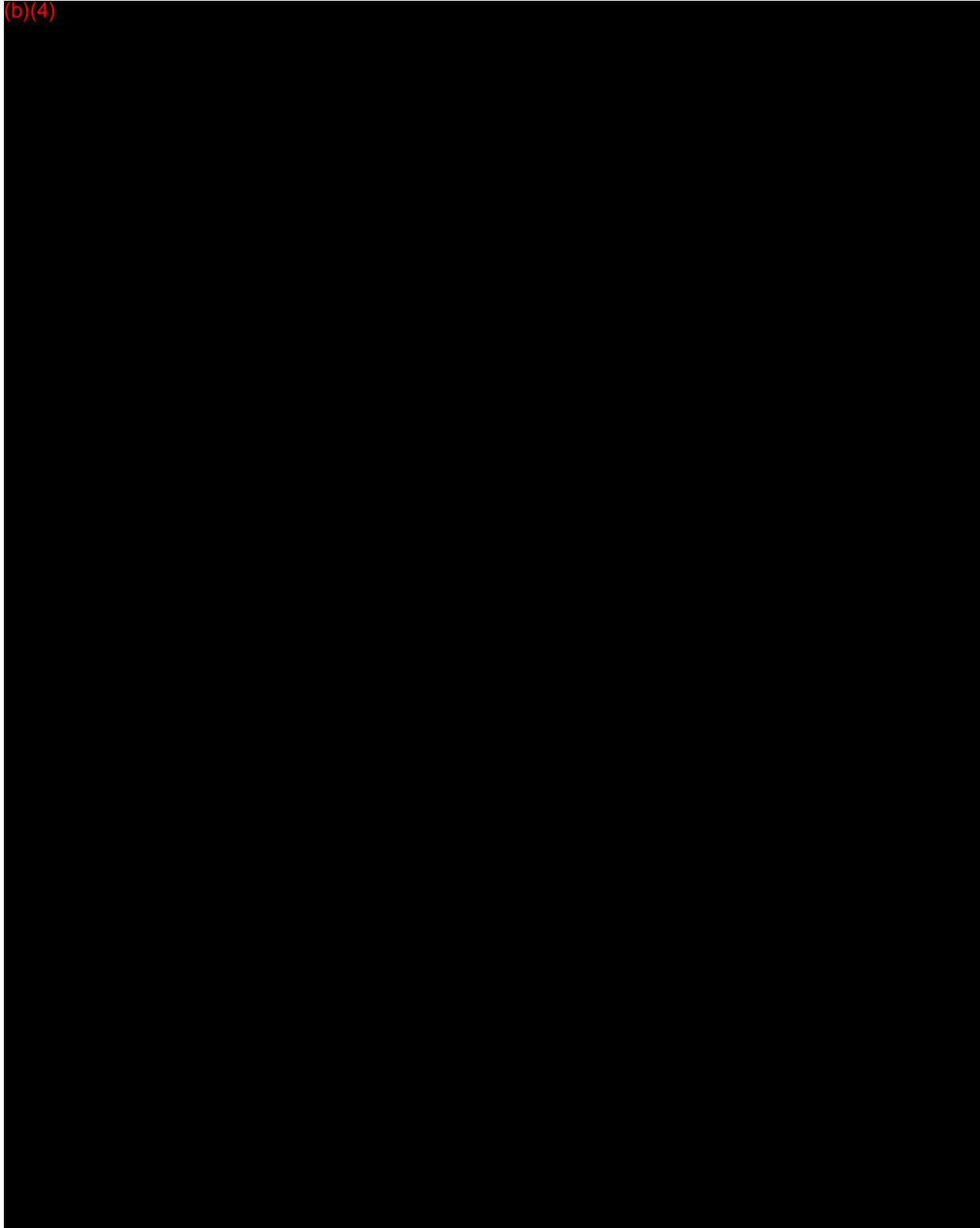
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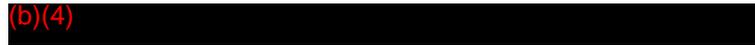
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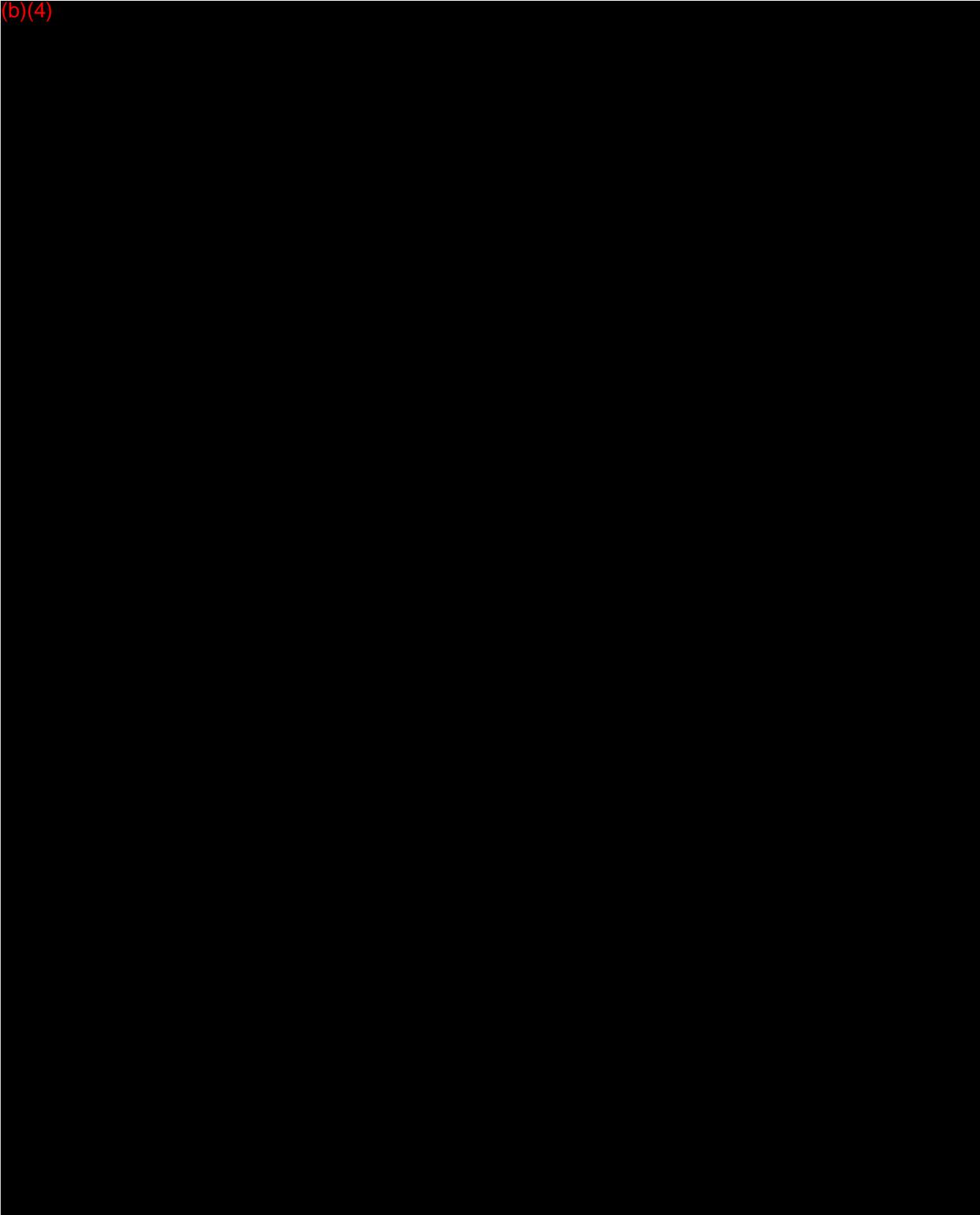
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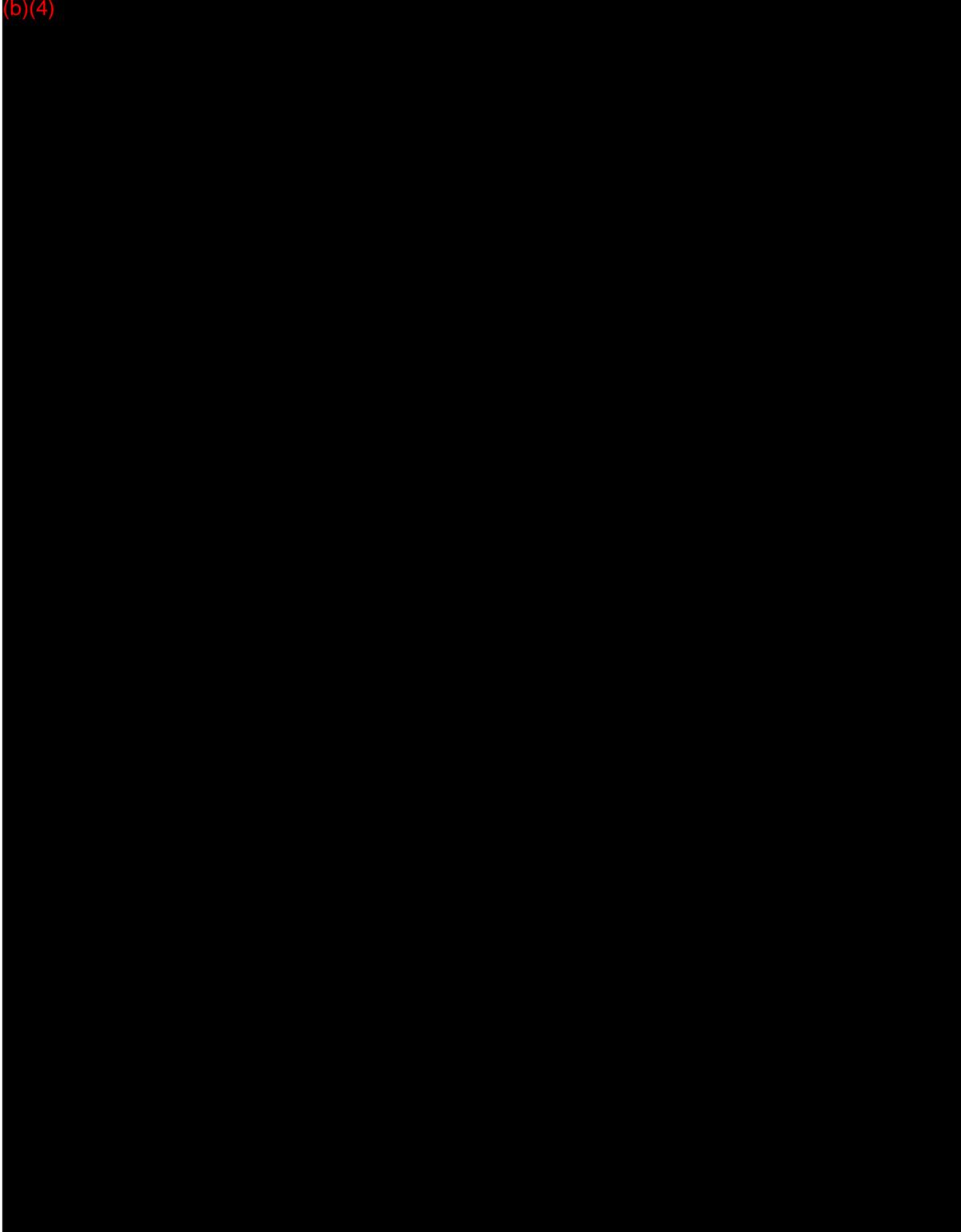
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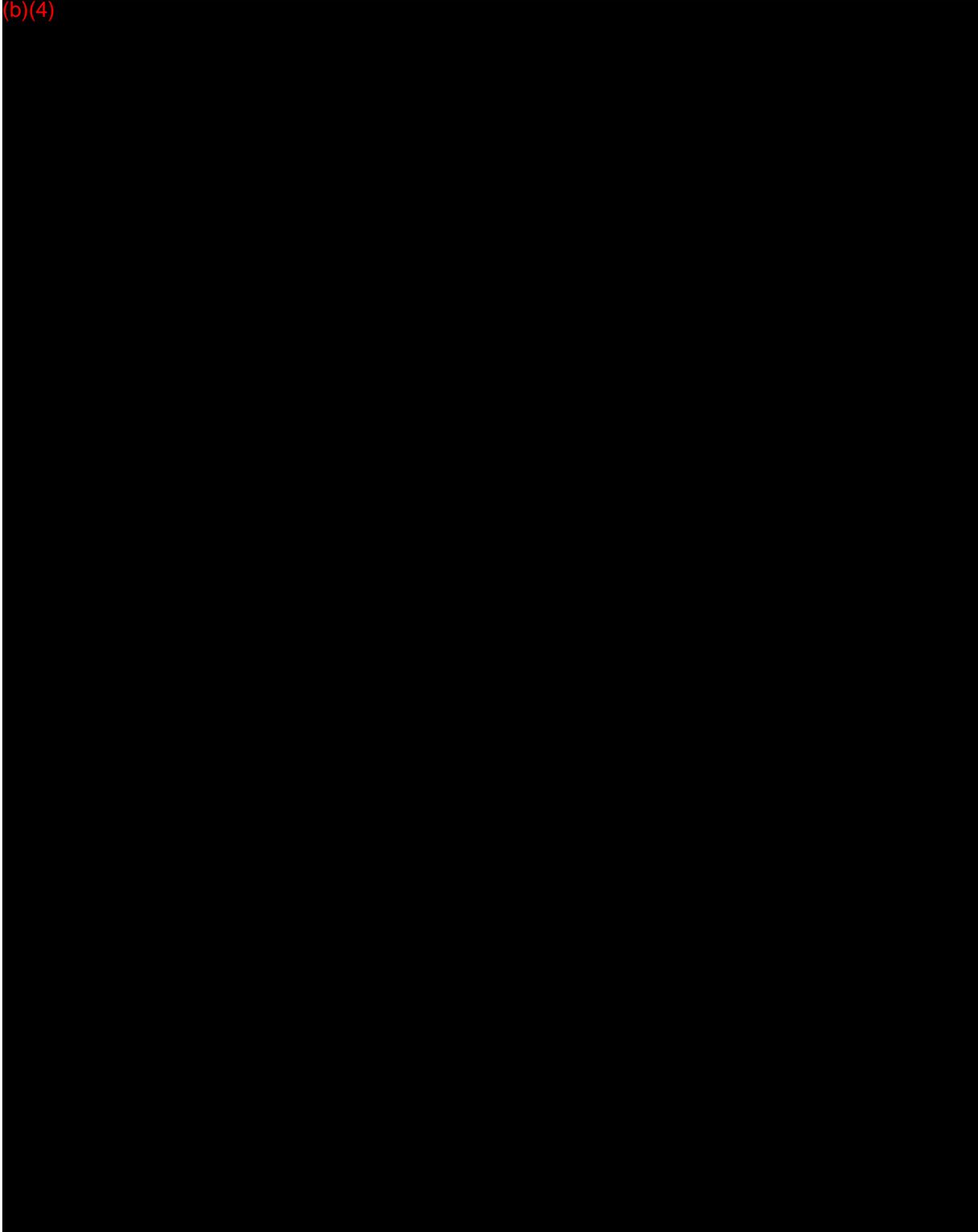
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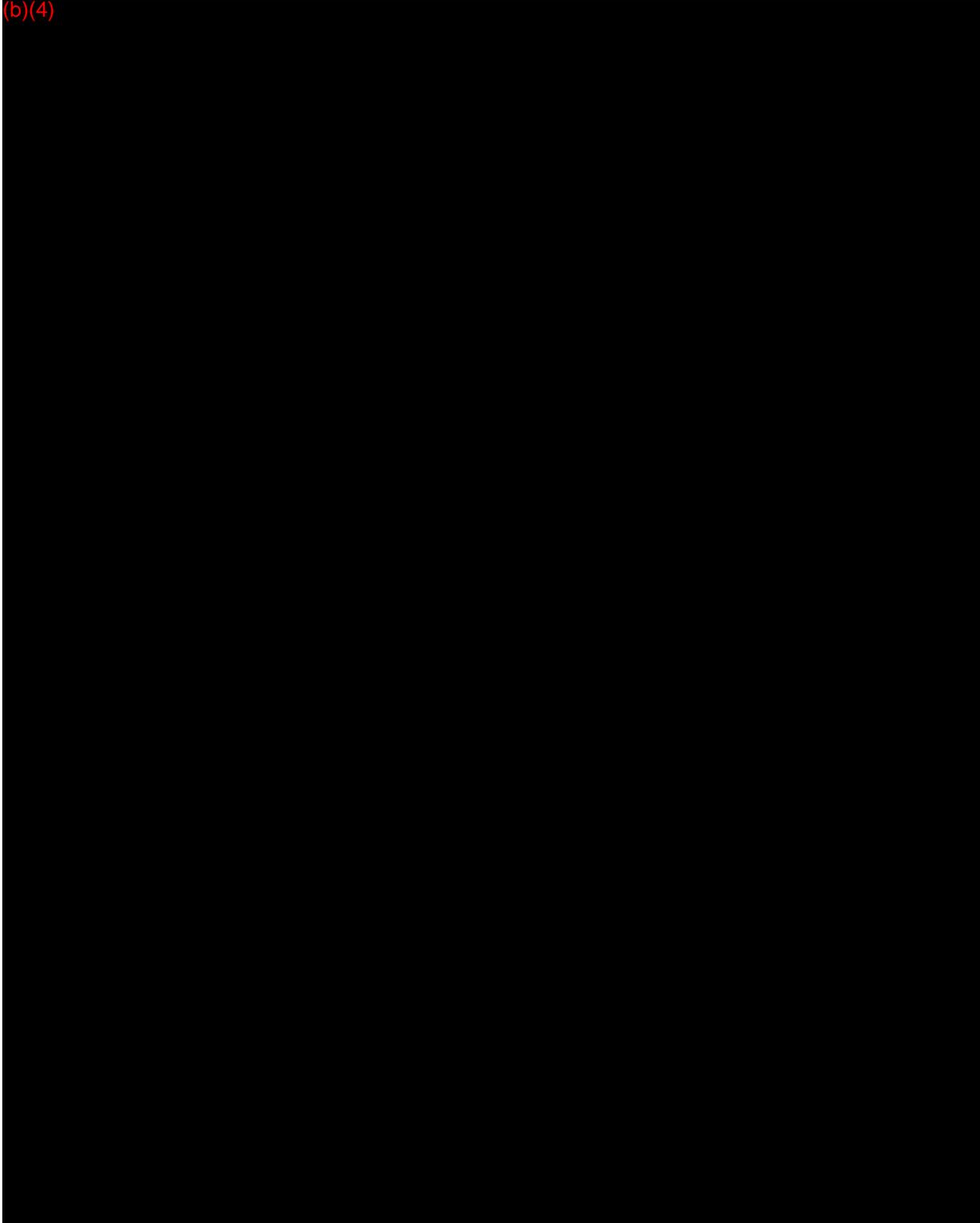
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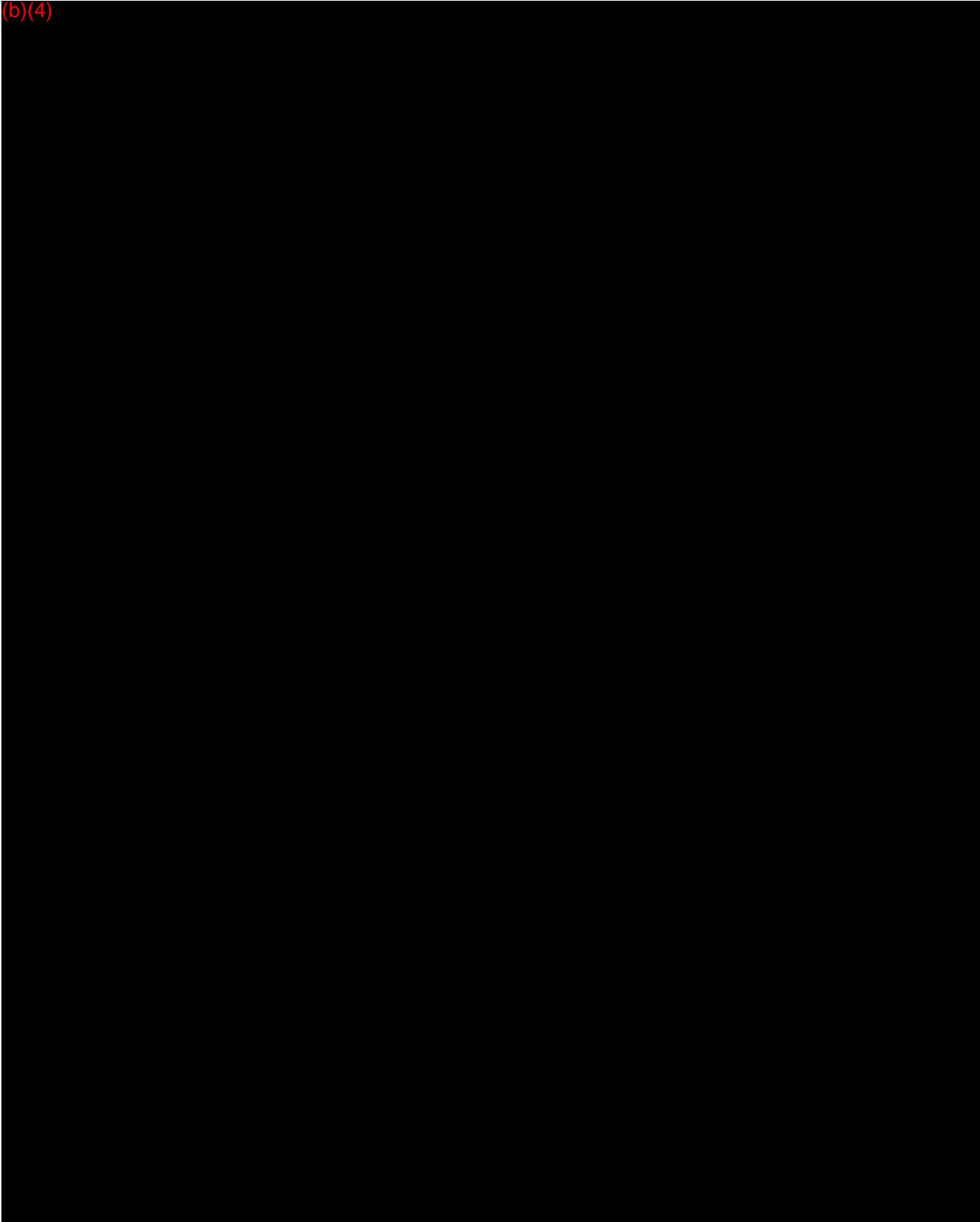
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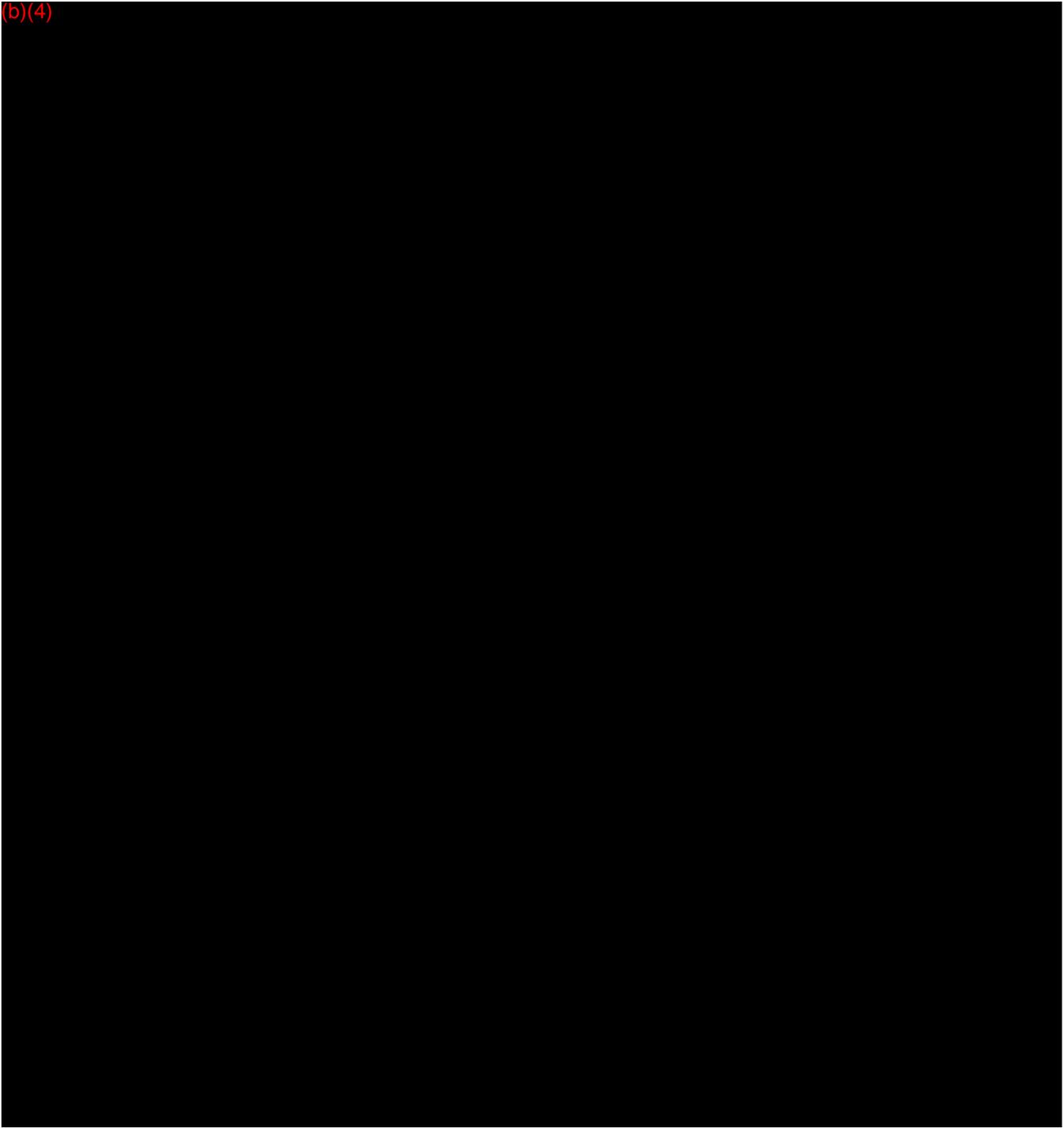
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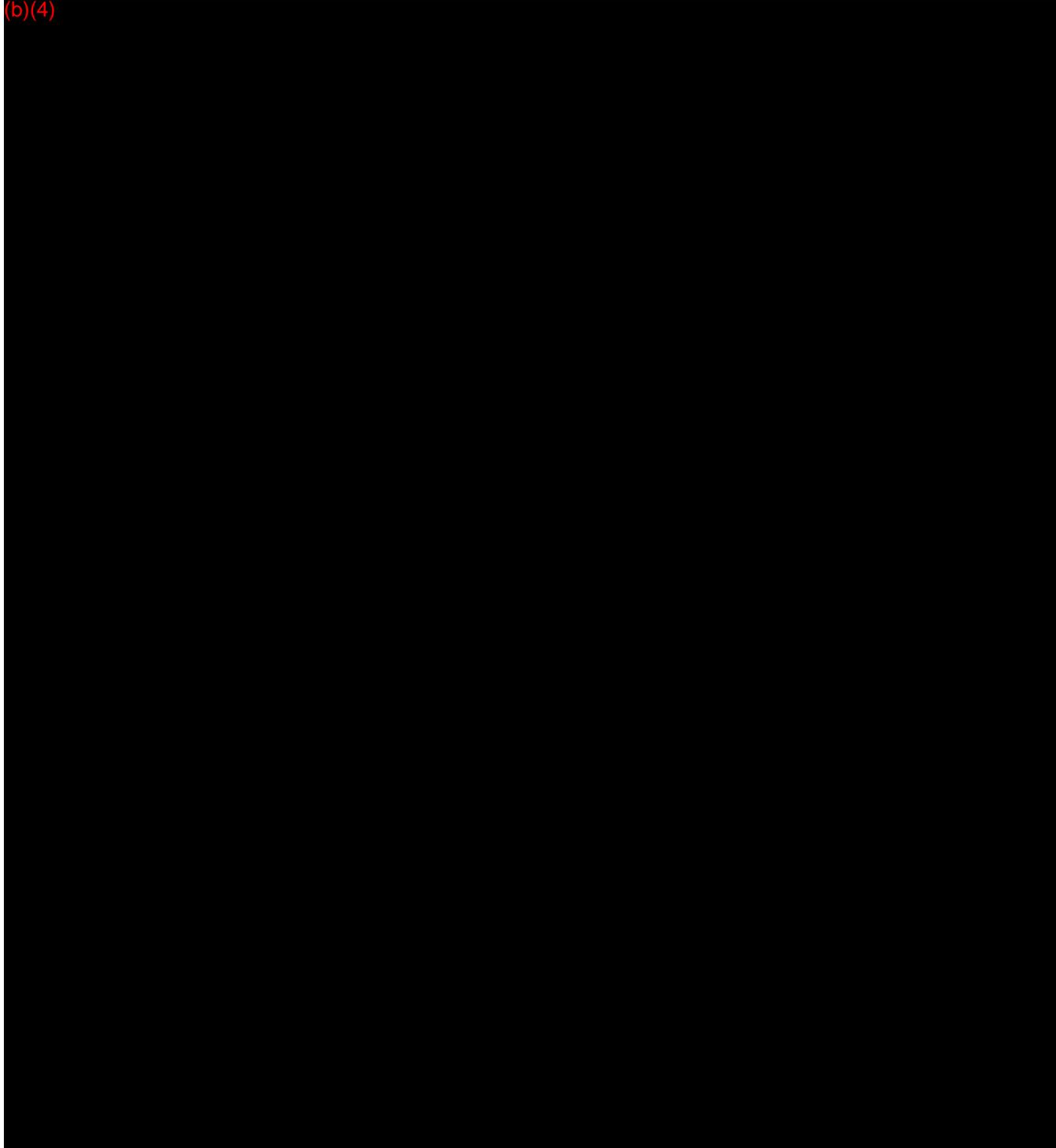


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Confidential Proprietary Information

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**COVER SHEET MEMORANDUM**

From: Reviewer Name
Subject: 510(k) Number
To: The Record

James Che
K120301

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%20202007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE) SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Special**

K120301

Date: February 23, 2012

To: The Record

Office: Office of Device Evaluation

From: James Cheng, DCD/CEMB

Division: Division of Cardiovascular Devices

510(k) Holder: St. Jude Medical, Inc.

Device Name: MediGuide Technology System

Contact: Mr. Jonathan S. Kahan, Esq., Hogan Lovells US LLP

Tel: (202) 637-5794

Fax: (202) 637-5910

Email: jonathan.kahan@hoganlovells.com

This Special 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable:

- 1. The name and 510(k) number of the SUBMITTER'S previously cleared or preamendments device: St. Jude Medical Guided Medical Positioning System II (gMPS™ II) cleared under K102905**
- 2. Submitter's statement that the INDICATION/INTENDED USE of the modified device as described in its labeling HAS NOT CHANGED along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.**

Indication for Use: Provided (see review memo).

- 3. A description of the device MODIFICATION (S), including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the FUNDAMENTAL SCIENTIFIC TECHNOLOGY of the modified device has not changed. Provided (see review memo).**
- 4. Comparison Information (similarities and differences) to applicant's legally marketed predicate device including labeling, intended use, formulation, physical characteristics, and certificates of analysis. Provided (see review memo).**
- 5. A Design Control Activities Summary which includes:**
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.**

- b) **Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.**
- c) **A declaration of conformity with design controls. The declaration of conformity should include:**
 - i) **A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and**
 - ii) **A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR § 820.30 and the records are available for review.**

Provided (see review memo).

6. Administrative Requirements

	Yes	No/ Inadequate	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Summary Elements per 807.92			
(1) Submitter's name, address, telephone number, contact person and	X		
(2) Name of the device including trade or proprietary name if applicable, the common or usual name, and the classification name if known.	X		
(3) Legally marketed predicate device	X		
(4) Device description	X		
(5) A statement of intended use	X		
(6) If the device has the same or different technological characteristics as compared to the predicate device.	X		
(6) An assessment of performance data.	X		
(b) (1) non-clinical tests			
(6)(b)(2) Assessment of the clinical tests submitted			X
(6)(b)(3) Conclusions drawn from non-clinical and clinical tests that demonstrate that the device is as safe and effective as the predicate	X		
Standards Form	X		
Clinical Trials Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? (Both) Are "cleaning" instructions included for the end user?	X		

Substantial Equivalence Discussion:

	Yes	No	
1. Same Indication Statement?	✓		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	✓		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Decision:

Conclusion/Recommendation

The submitter's description of the particular modification(s) and the comparative information between the modified and unmodified device demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in *The New 510(k) Paradigm* and on this basis; I recommend the device be determined substantially equivalent to the previously cleared device.

Regulation Number: 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: II (2)
Product Code: DQK

James Chen

Reviewer

Mark Roberto Aguel

Chief
Cardiac Electrophysiology & Monitoring Devices Branch

2/23/12
Date

2/23/12
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Memorandum

MEMO RECORD

From: James Cheng *JMC 2/23/12*
To: K120301
Subject: St Jude Medical, Inc.
MediGuide Technology System Special 510(k)

Date: 2/23/12
Office: ODE
Division: DCD

SUMMARY

Contact Person

St. Jude Medical, Inc.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
Tel: (202) 637-5794
Fax: (202) 637-5910
Email: jonathan.kahan@hoganlovells.com

Device Trade Name: MediGuide Technology
Classification Name: Programmable diagnostic computer
Regulation Number: 870.1425
Product Code: DQK
Class: II (2)

St. Jude Medical is submitting this Special 510(k) notice to address modifications to the cleared MediGuide Navigation Systems/Guided Medical Positioning System II (gMPS II) (K102905). This

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The MediGuide Technology System is used in conjunction with an X-ray System and employs magnetic positioning technology to track a MediGuide enabled diagnostic or therapeutic invasive device for the 3D position relative to any X Ray image, in real-time or previously recorded cine-loop.

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INDICATIONS FOR USE

The MediGuide Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide enabled (equipped with a MediGuide sensor) diagnostic or therapeutic invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

This is stated by the sponsor to be the same intended use as previously cleared for the gMPS™ II system, except for the change in the name of the system.

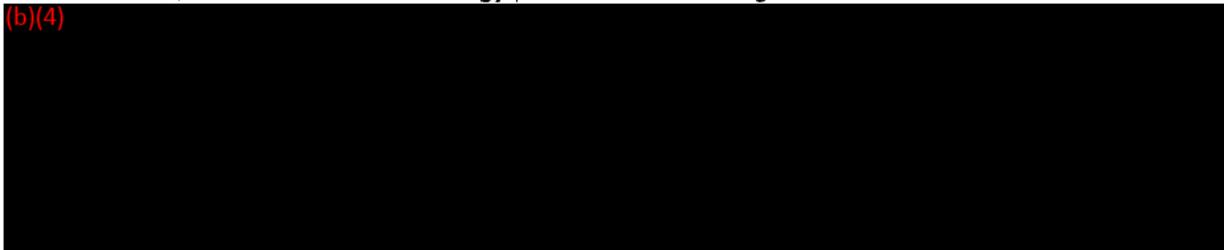
DEVICE DESCRIPTION

The MediGuide Technology System, used in conjunction with an X-ray System, employs magnetic positioning technology to track a MediGuide enabled diagnostic or therapeutic invasive device for the 3D position relative to any X-Ray image, in real-time or previously recorded cine-loop.

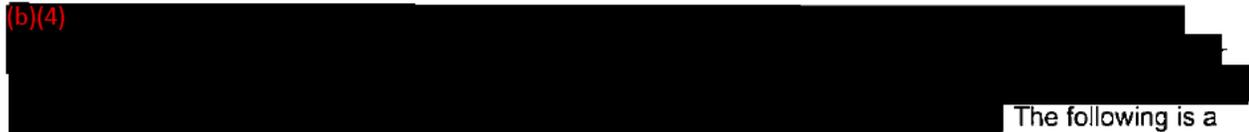
The MediGuide Technology System includes two optional software packages. The Coronary package includes the Coronary application, and it supports coronary procedures. The Cardiac package includes the Cardiac Navigation application and the Cardiac Navigation with Angio Survey™ application, both support cardiac procedures.

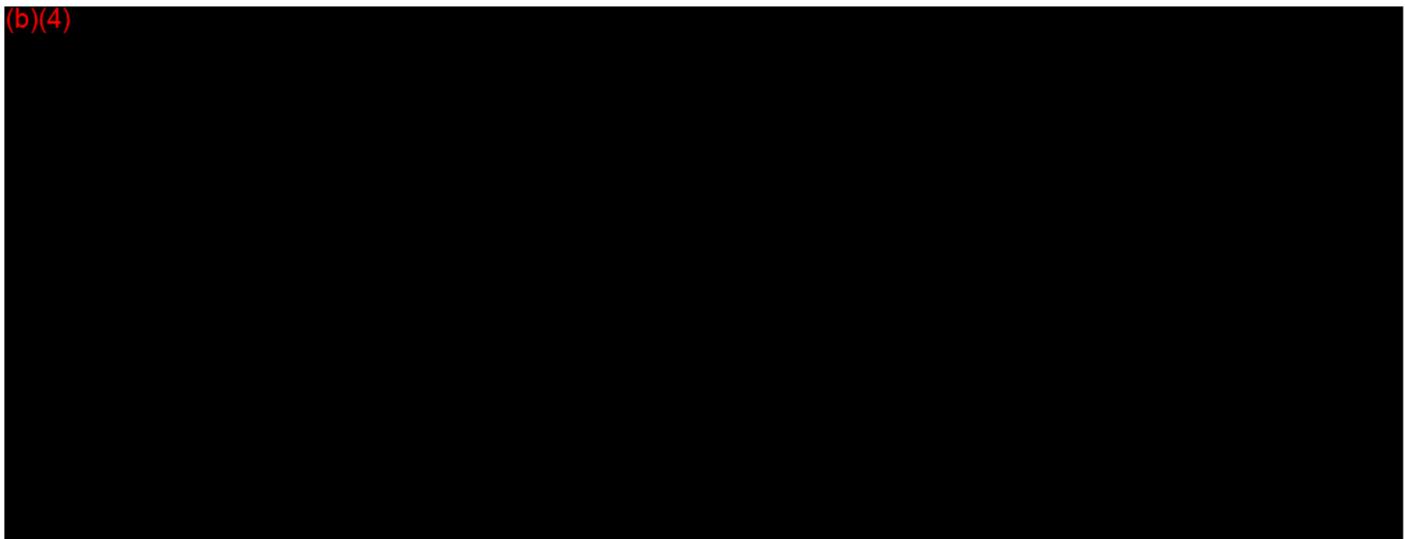
The most fundamental capability of the MediGuide Technology is the positioning and navigation of MediGuide enabled devices. This feature enables projection of the real time position of a MediGuide sensor (and thus of the MediGuide enabled device) on real time 2D X-Ray images (live mode) or in a recorded mode (the MediGuide enabled device tip real time position is superimposed on a previously recorded cine loop or still image). The MediGuide Technology enables simultaneous tracking of up to three MediGuide enabled devices.

In addition, the MediGuide Technology provides the following features:

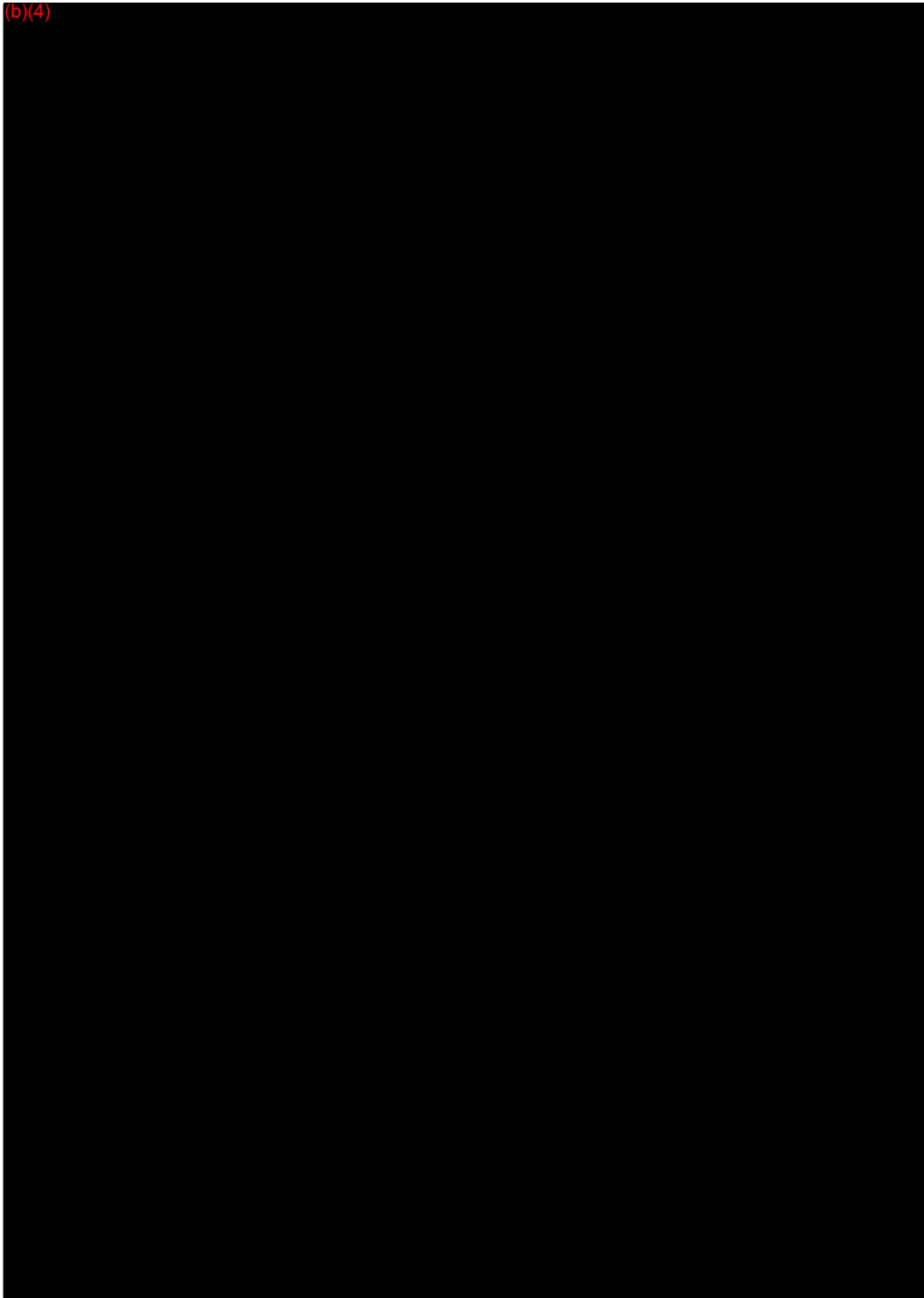
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MODIFICATIONS

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 The following is a summary of the key modifications:

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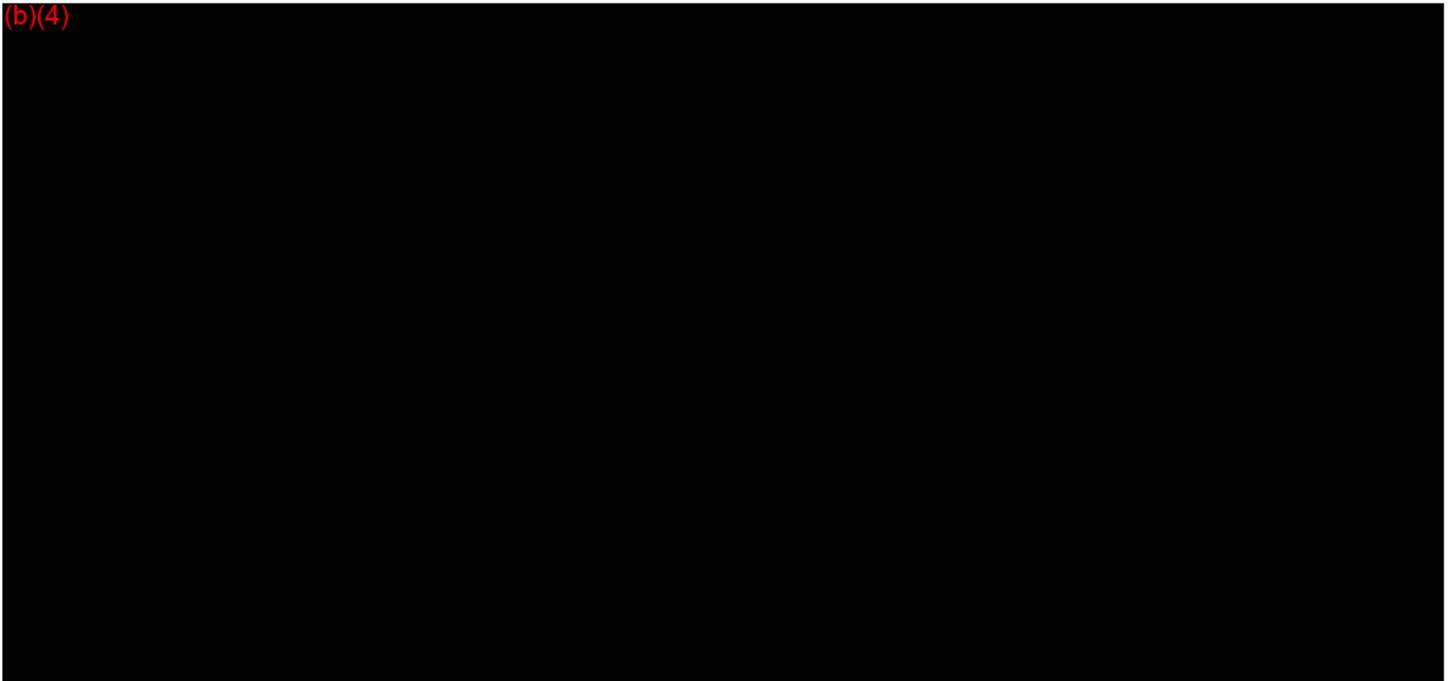


PREDICATE DEVICES

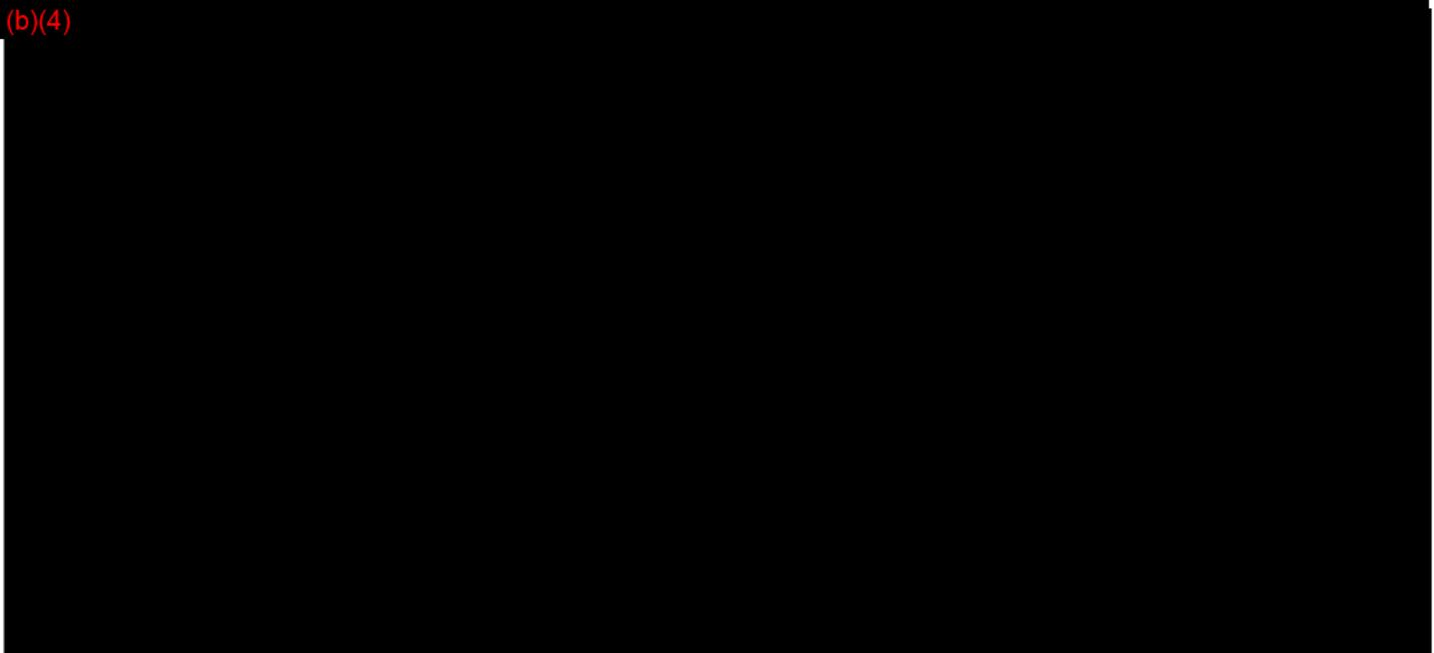
St. Jude Medical Guided Medical Positioning System II (gMPS™ II) cleared under K102905.

MODIFICATIONS

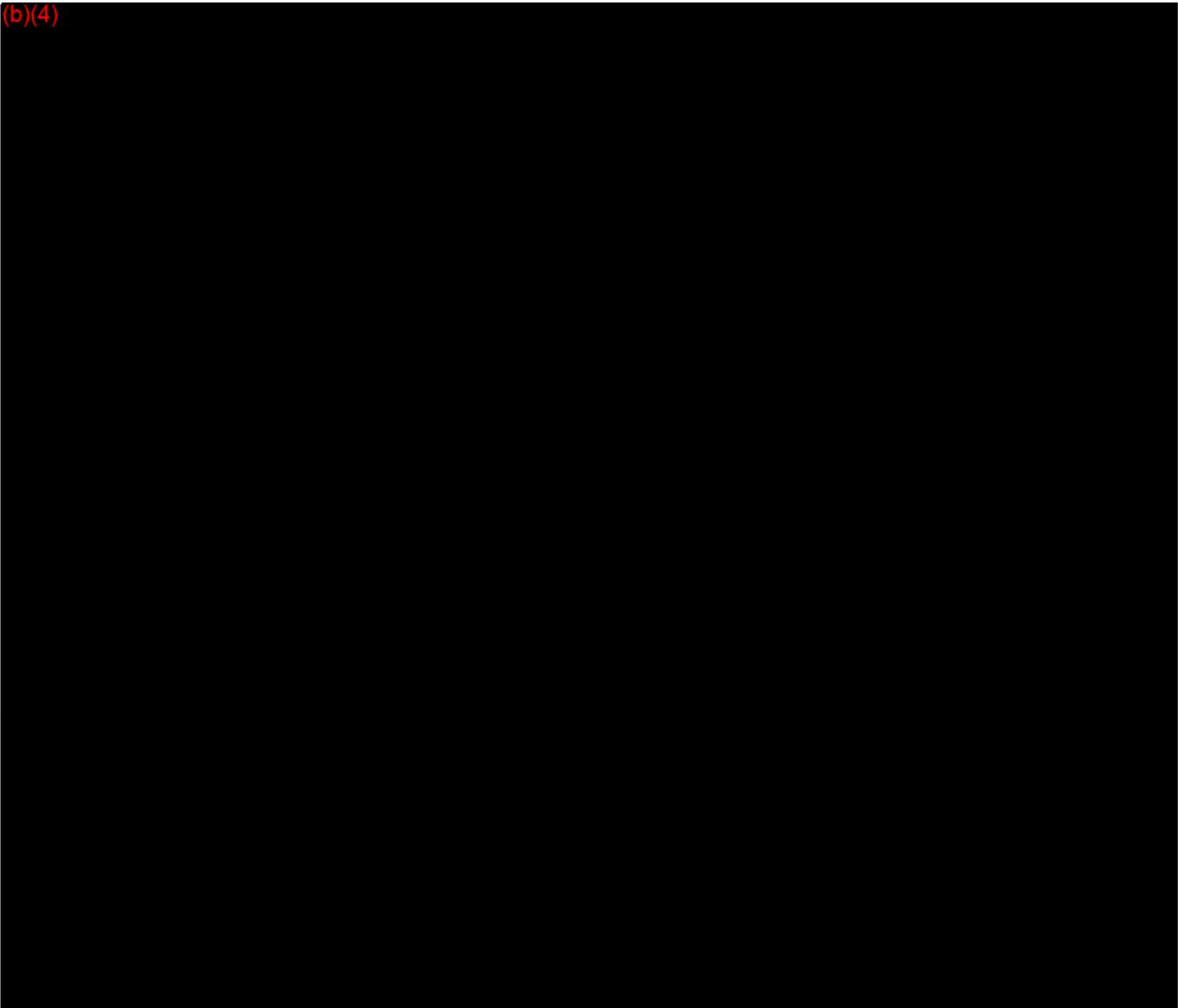
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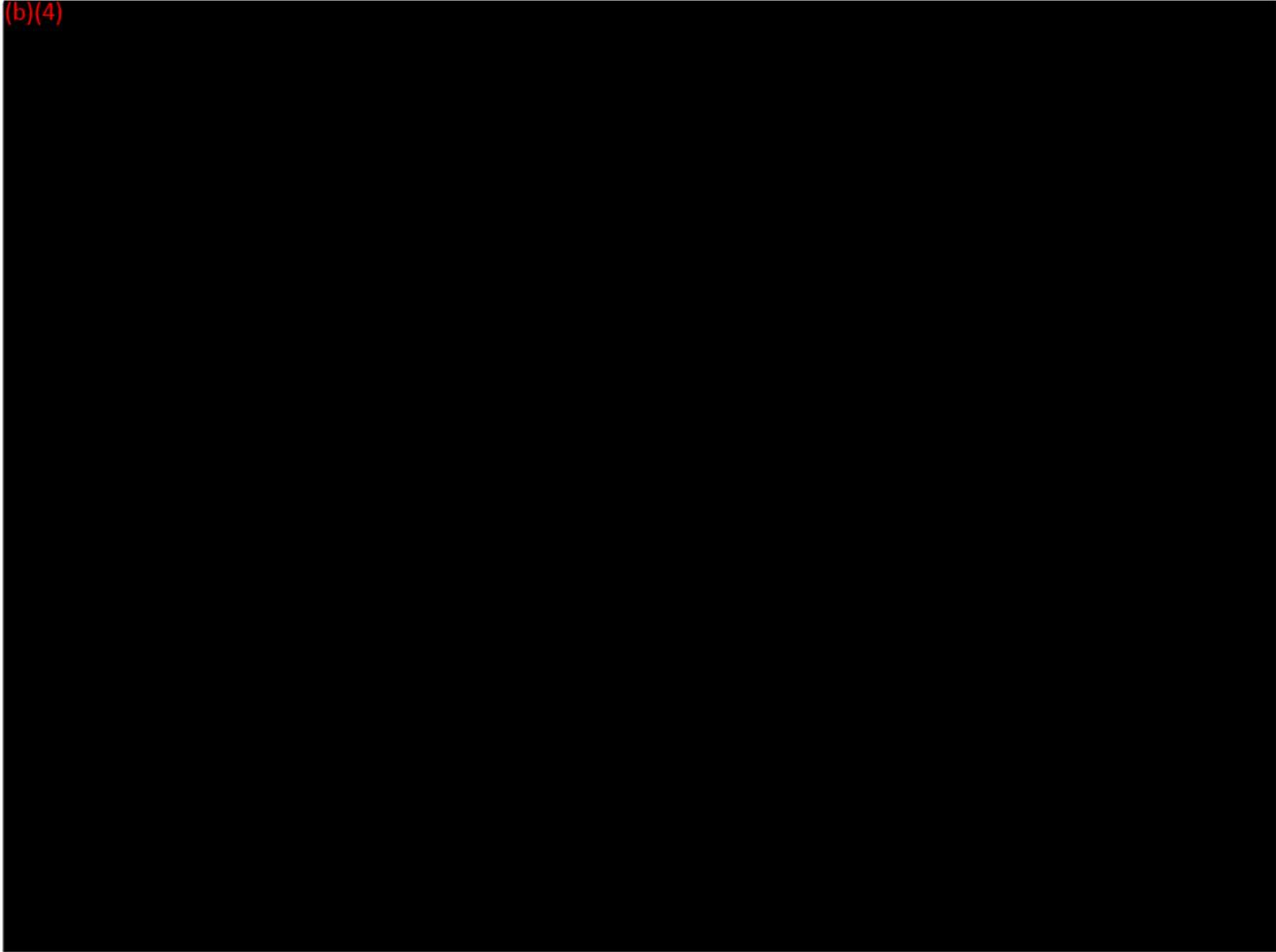
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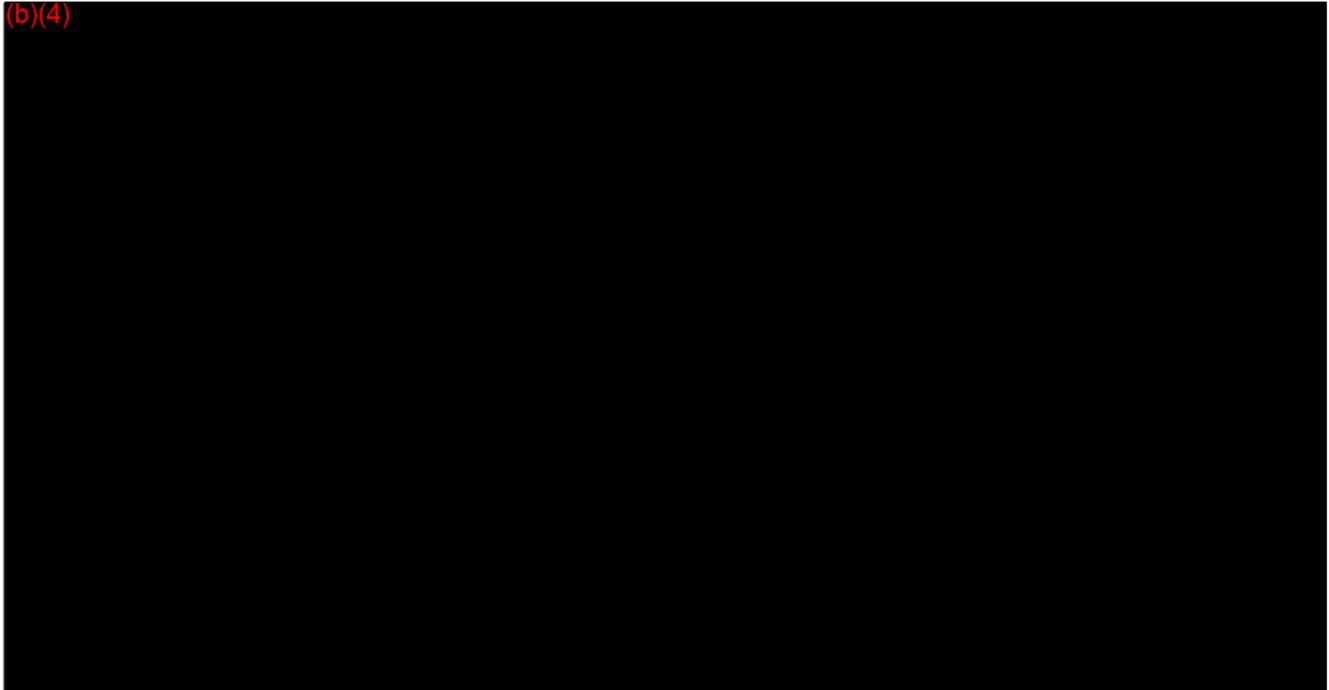
Software features

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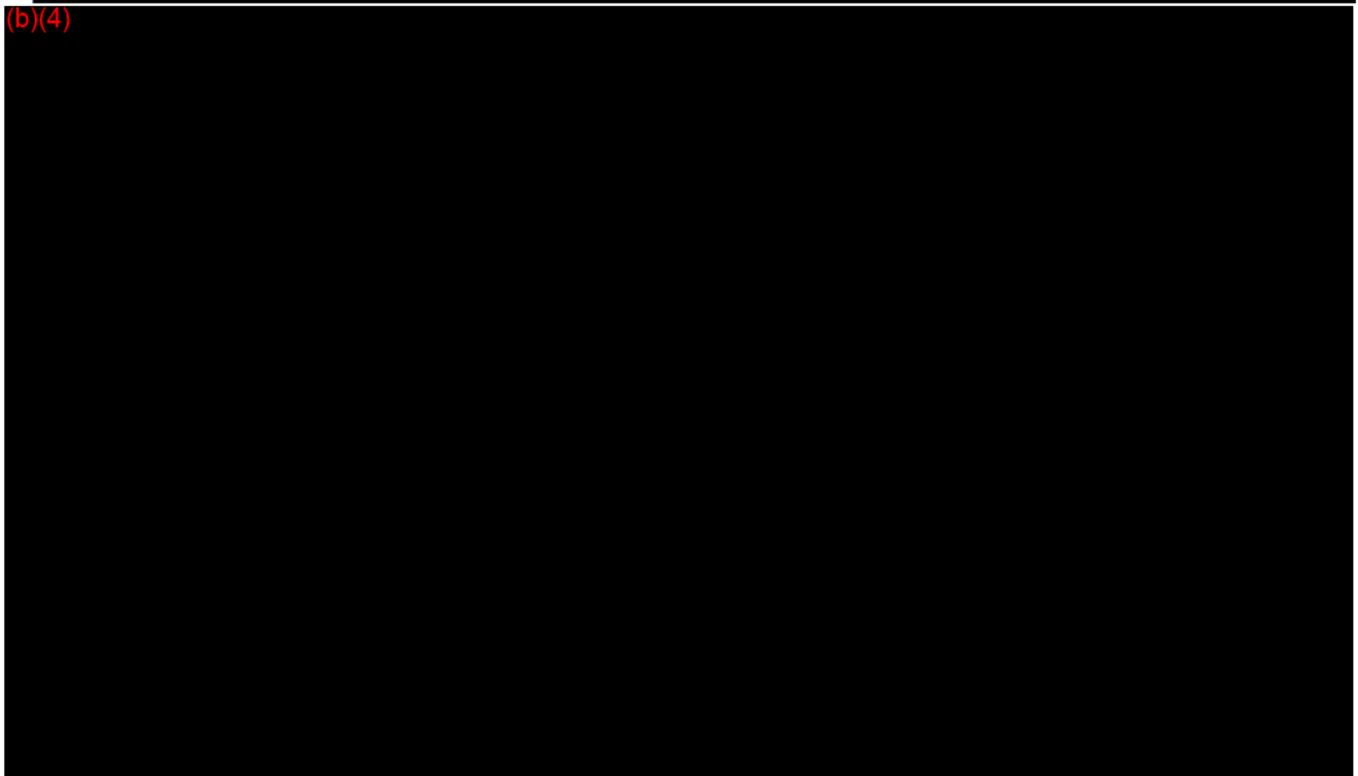
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PERFORMANCE

The following design control activities were performed in order to verify that the modified MediGuide Technology system has comparable performance and safety as compared to the cleared device:

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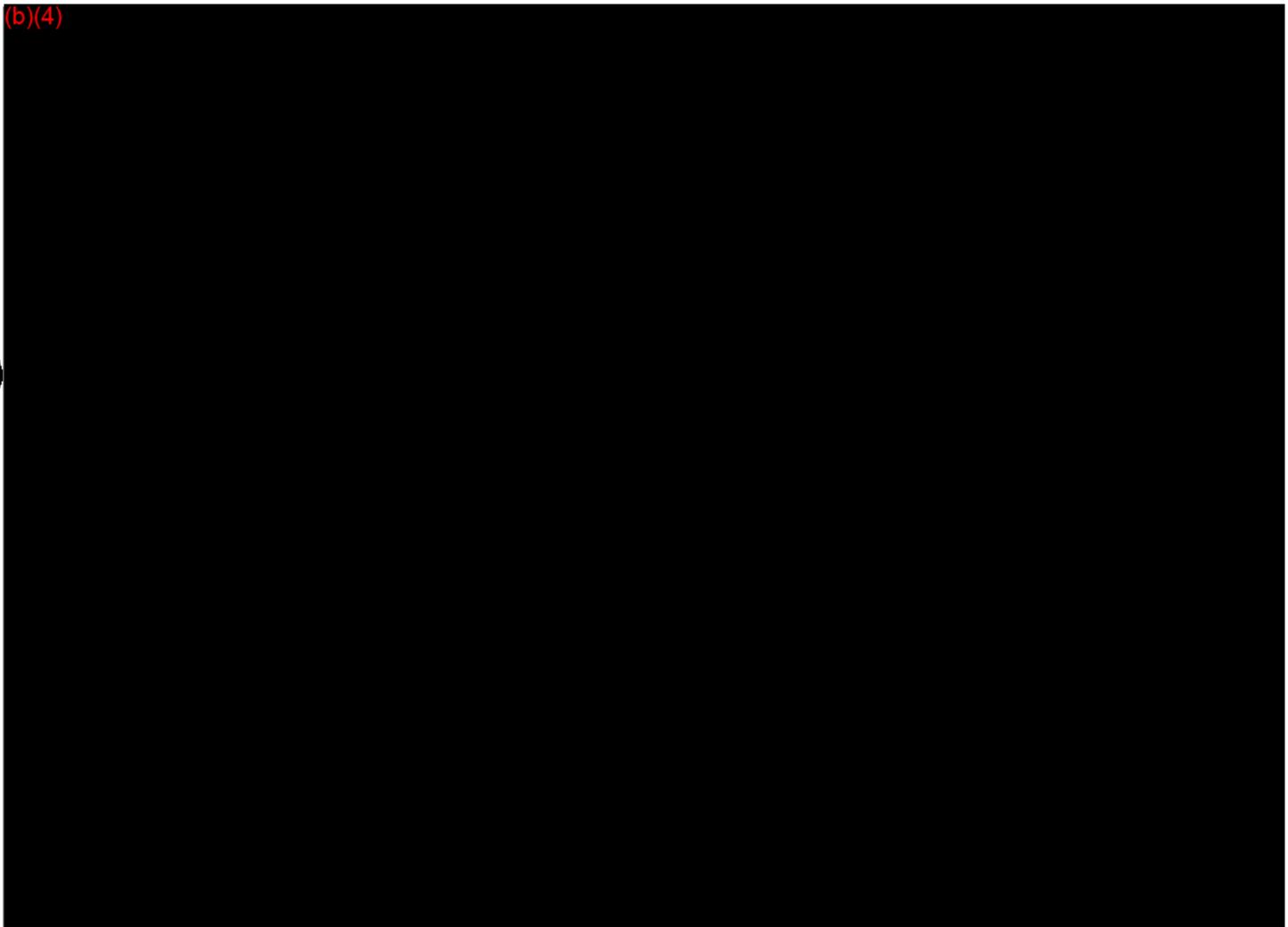


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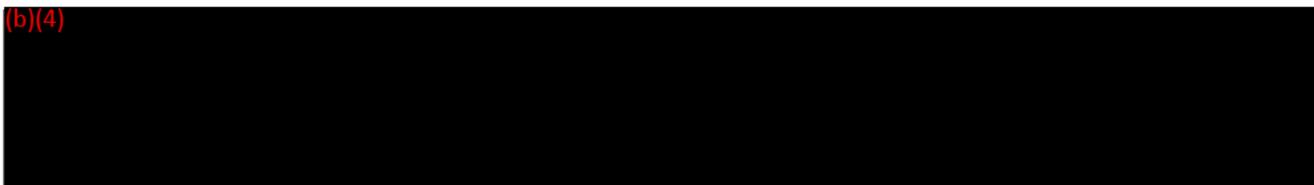
SOFTWARE

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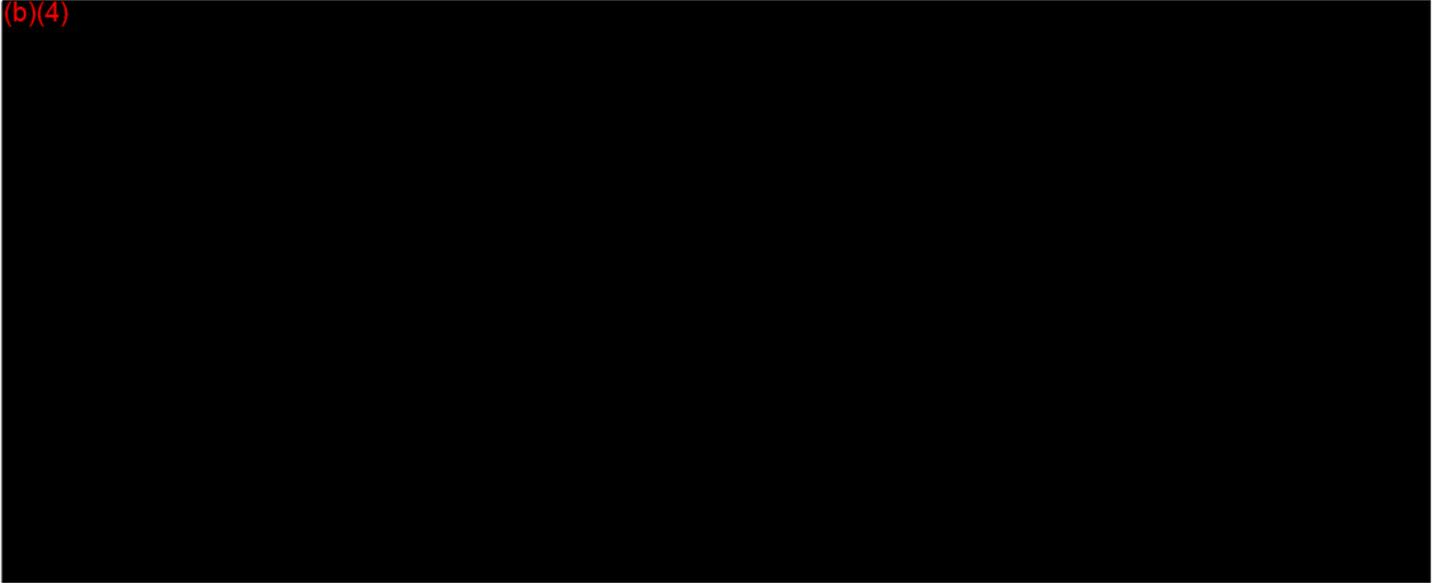
Level Of Concern

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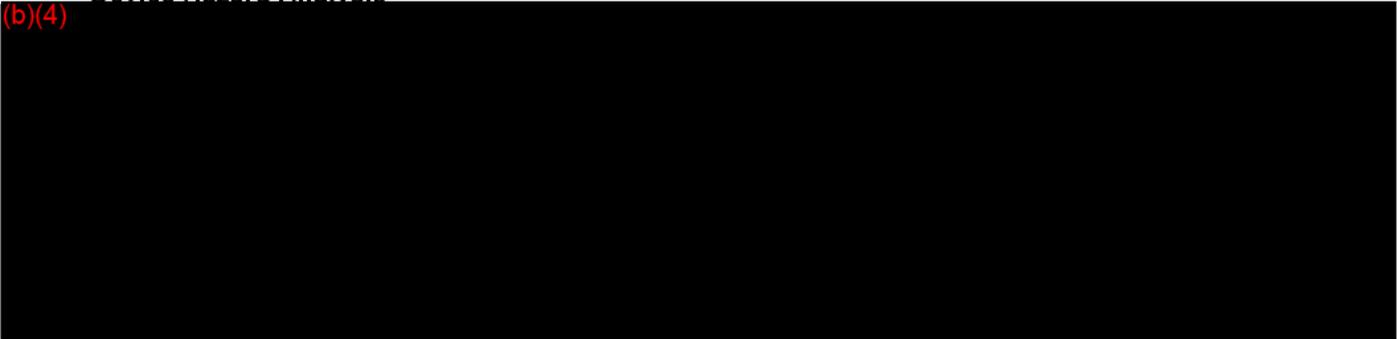
Software Description

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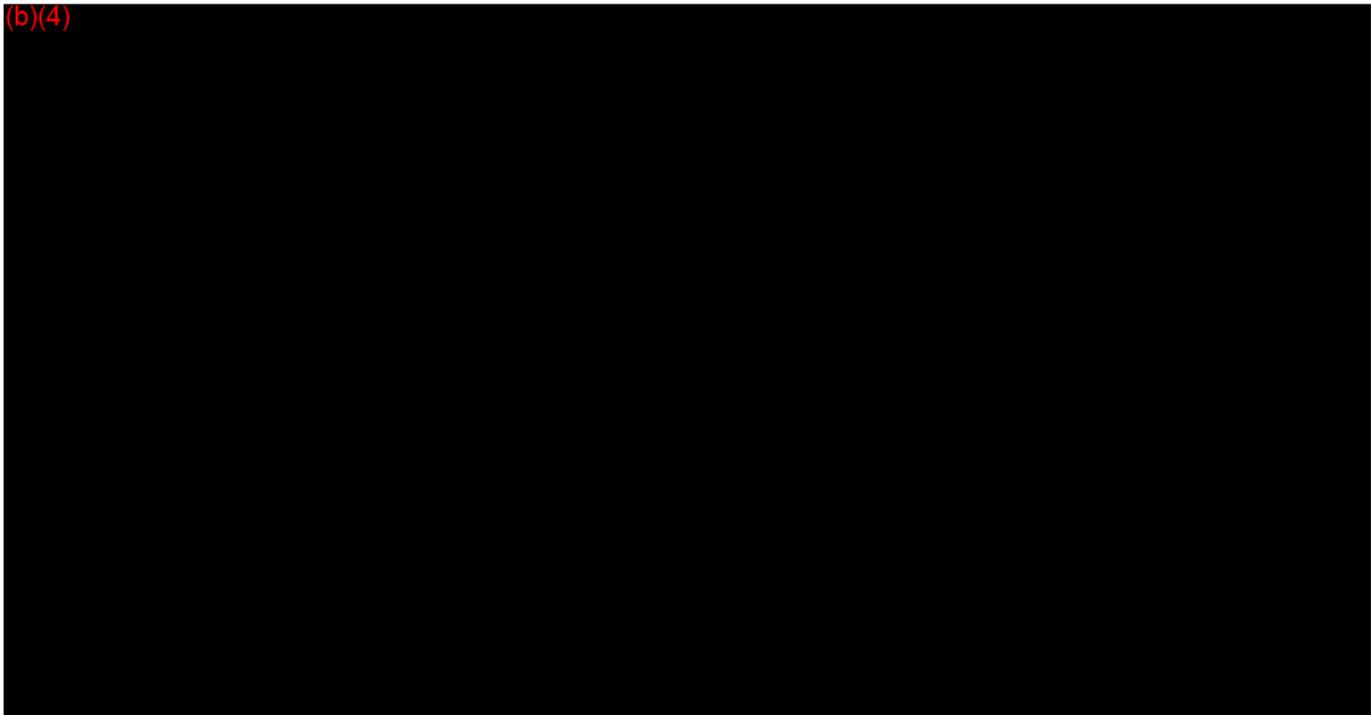
Device Hazard Analysis

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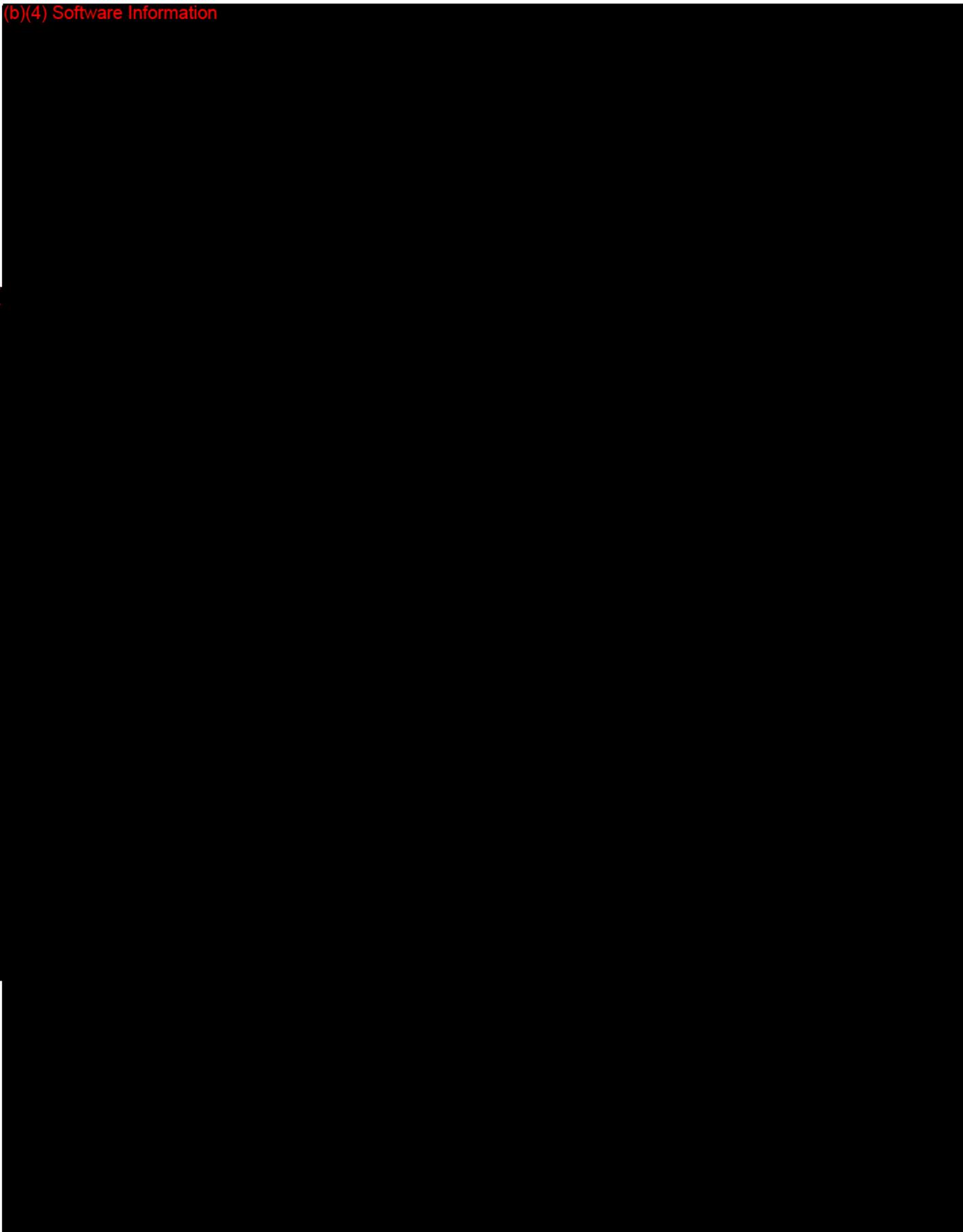


Software Requirement Specification

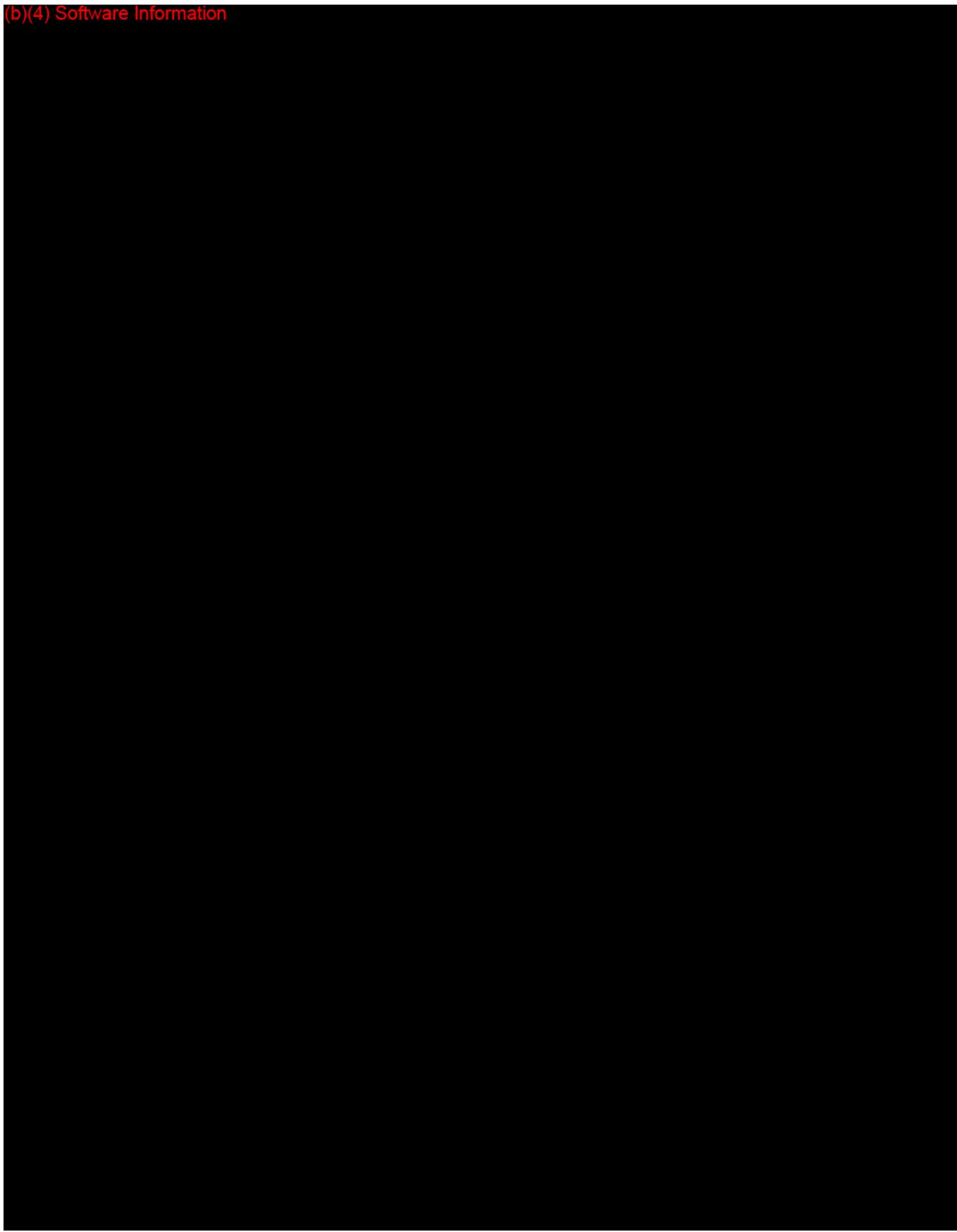
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(b)(4) Software Information



(b)(4) Software Information



Software Documentation

The submitted information is appropriate and acceptable for the stated level of concern.

CONCLUSION

The sponsor has provided appropriate and acceptable descriptions of the modifications made to the device. There are no issues with the information provided by the sponsor. Therefore, substantial equivalence is recommended.

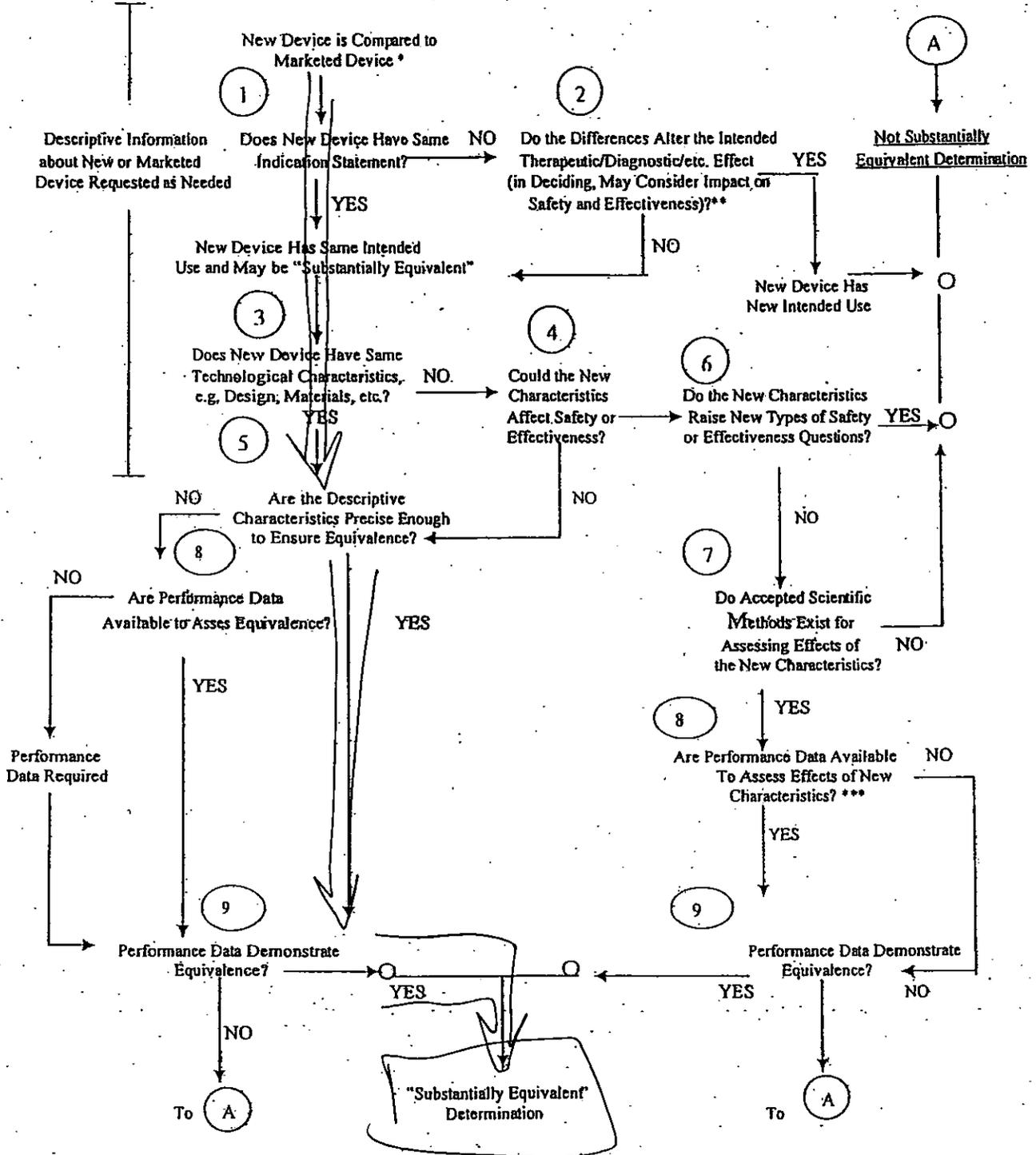
RECOMMENDATION

Substantial equivalence

ACTION

SE Letter

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data made in the 510(k) or the 510(c) by the Firm's submission files or the literature.