



MENTOR

**PRODUCT PERFORMANCE QUALIFICATION
 SUMMARY REPORT FOR THE SILTEX®
 MODERATE PROFILE ROUND GEL-FILLED
 MAMMARY PROSTHESIS**

A SUMMARY REPORT FOR PROCESS QUALIFICATION

The signature of the originator below certifies that all test functions and supporting documents required by the qualification protocol were completed, reviewed, and attached to this report. The signature also certifies that all amendments and deviations were documented, approved, and attached to this report.

Report Originated By:

<i>R. Guest</i>	12/9/98
Signature of Engineer	Date
R. GUEST, SENIOR STAFF ENGINEER, R&D	
Printed Name, Title, Department	

RET
12/19/98
RET
1/19/99
RET
4/27/99

The signatures of the managers below certify that the requirements of the protocol have been met, and the documentation supporting this report has been reviewed and found to be acceptable. The signatures also indicate that all deviations have been adequately resolved and that the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis is therefore qualified.

Report Approved By:

<i>Michael W. Witkowski</i>	12-17-98
Operations Signature	Date
Michael W. Witkowski, Director, Manufacturing Operations	
Printed Name, Title, Department	

JFA
4/21/99
1/19/99

<i>J. R. Barber</i>	12 Dec 1998
Research and Development Signature	Date
J. R. BARBER, V.P. OF R&D, RESEARCH & DEVELOPMENT	
Printed Name, Title, Department	

JRB
12/19/98
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12/19/98
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PRODUCT PERFORMANCE QUALIFICATION
SUMMARY REPORT FOR THE SILTEX® MODERATE PROFILE
ROUND GEL-FILLED MAMMARY PROSTHESIS

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	12/9/98	<i>R. Oakes</i> 12/11/98
Engineering Signature	Date	<i>John</i> 7/27/99
<i>Ralph Oakes, Engineering Manager - Manufacturing Support, Engineering</i>		
Printed Name, Title, Department		

<i>Ramon Ricart</i>	22 Dec 98	<i>R. Ricart</i> 12/27/98
Quality & Regulatory Assurance Signature	Date	<i>R. Ricart</i> 27 Apr 1999
<i>RAMON RICART, VP Q&RA</i>		
Printed Name, Title, Department		

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1.0 PURPOSE

This summary report documents the results of protocol HS33.980902.02, "Product Performance Qualification Protocol for the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis", performed at the Mentor facility in Irving, TX. A copy of the executed protocol is attached to this report.

This report has been prepared under the guidelines established by the Mentor Quality Manual. This report will provide documented evidence that the manufacture of the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis complies with corporate standard operating procedures, meets the requirements of current Good Manufacturing Practices (cGMP) and FDA regulatory obligations, and repeatably and reproducibly produces product that meets predetermined specifications.

2.0 SCOPE

This report summarizes the results of the product performance activities associated with the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis. This report will also provide documented evidence that the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis is qualified and meets finished device specifications.

3.0 RESPONSIBILITIES

3.1 Originator

- A. Prepare and write this final report.
- B. Assemble the test data and attachments and review the data and attachments for accuracy and acceptable completion.

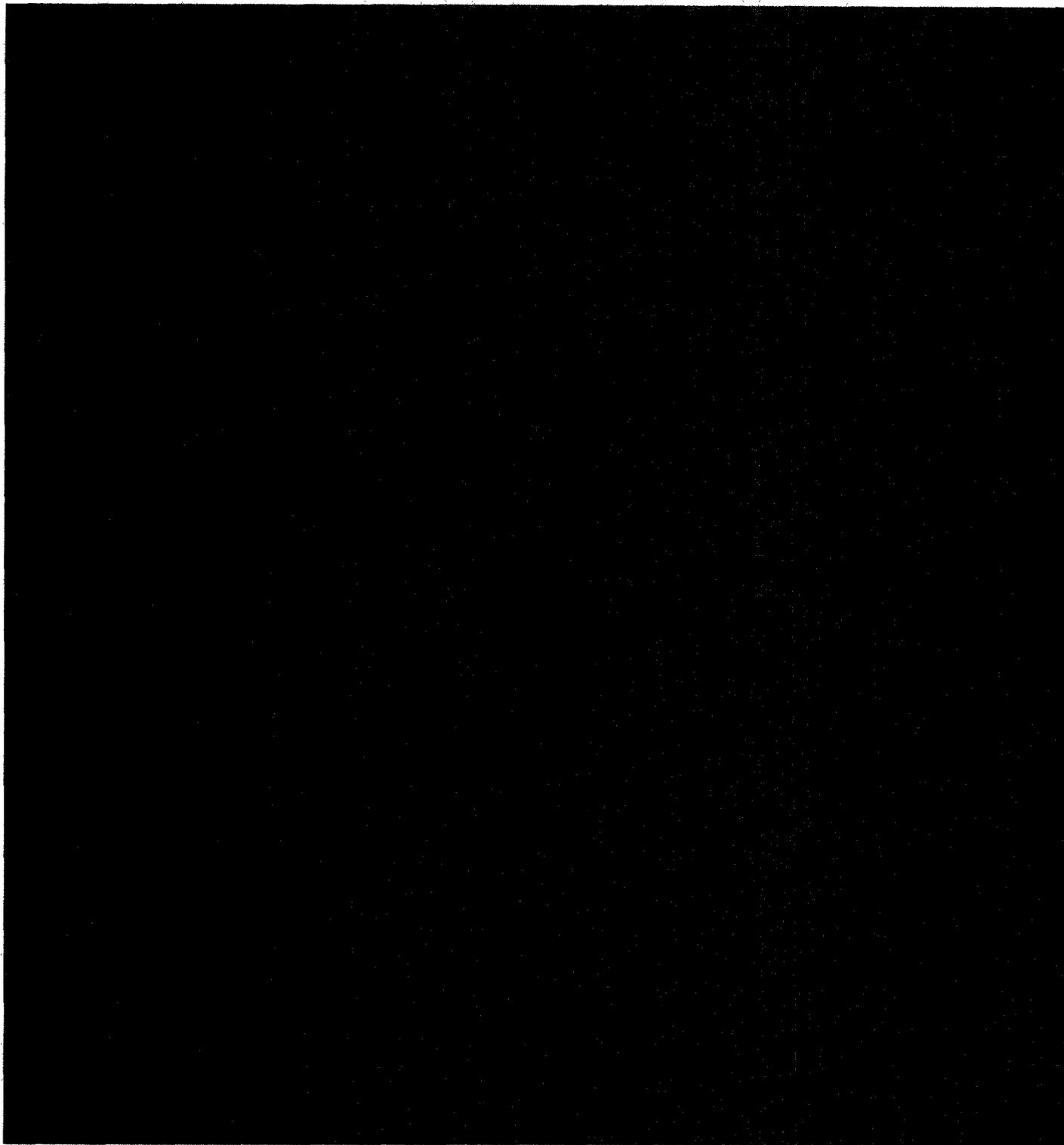
3.2 Management

- A. Review and approve this report according to the certification requirements indicated on the cover pages.

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4.0 Process Flowchart



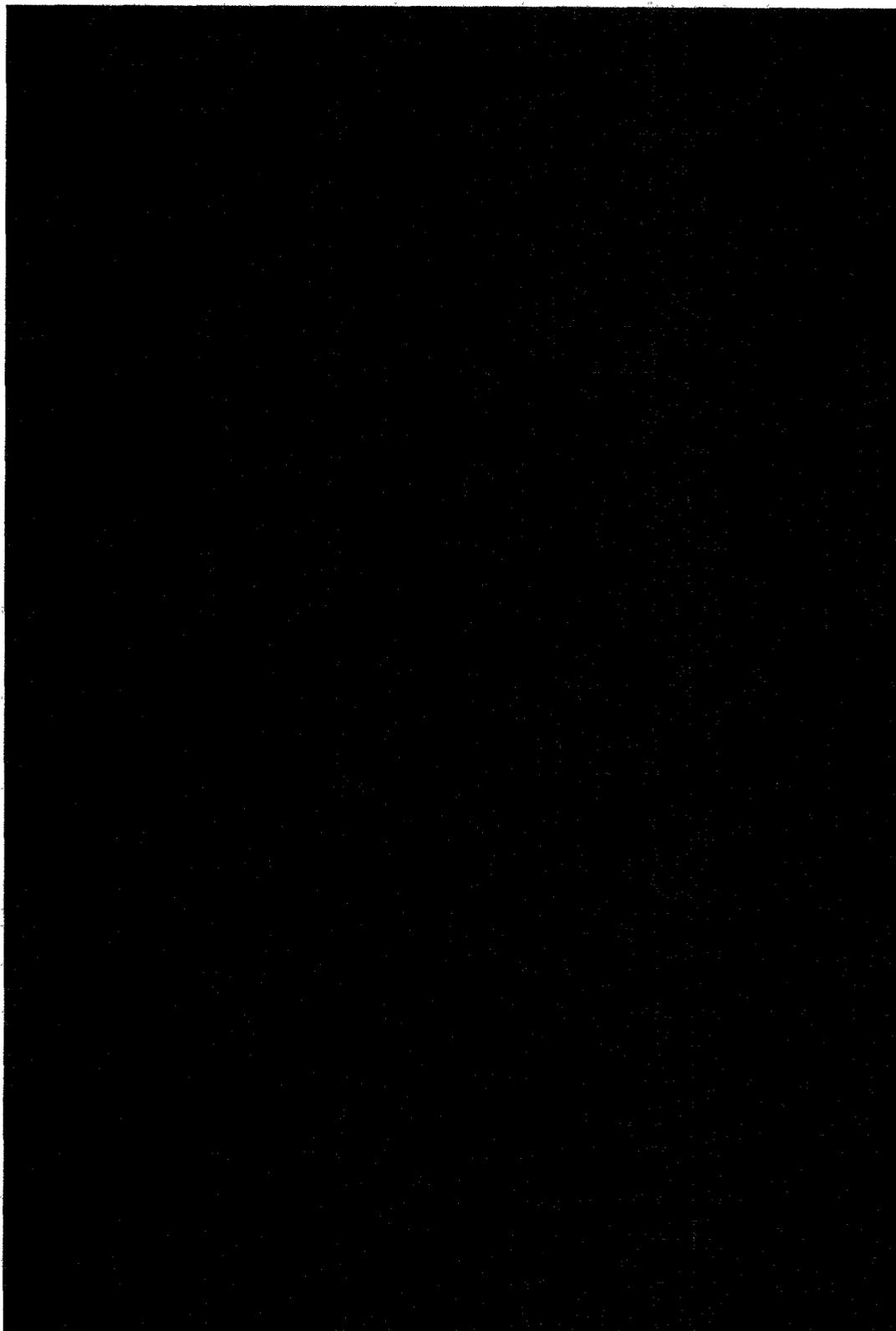
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5.0 RESULTS

The following matrix lists the Main Assembly and catalog level shop order numbers for the six trials run during the execution of protocol number HS33.980902.02, "Product Performance Qualification Protocol for the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis".

**Table #1
 Lot Number Matrix**

Catalog Part Number	PPO Trial Number	Main Assembly Lot Number	Catalog Level Lot Number
354-1007	1		184271
354-8007	2		184274
354-1007	3		184272
354-8007	4		184275
354-1007	5		184273
354-8007	6		184276

The following table documents the results of the product performance activities performed during the execution of protocol number HS33.980902.02, "Product Performance Qualification Protocol for the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis".

**Table #2
 Process Qualification Results**

Protocol Attachments	Results	Conforms? (Yes/No)
Attachment #1: Signature List	All persons involved in the execution of the protocol have completed this section.	Yes
Attachment #2: Document Verification	All documents necessary for the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis Manufacturing Process are included.	Yes
Attachment #3: Material Verification	All materials used in this qualification have been purchased and procured according to Mentor SOP's, and PQA inspection/testing is available for all lots.	Yes

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Table #2 (Continued)
Process Qualification Results

Protocol Attachments	Results	Conforms? (Yes/No)
Attachment #4: Instrumentation Verification – Component Assembly	All instrumentation used in Component Assembly during this qualification was precision calibrated at the time of use. Copies of the precision calibration certificates are attached to the executed attachment.	Yes
Attachment #5: Process Equipment Verification – Component Assembly	All equipment used in Component Assembly during this protocol has been qualified, and a qualification summary report for each is on file in the Mentor Library.	Yes
Attachment #6: Process Qualification Verification	All of the manufacturing processes used to produce the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis for this qualification have been qualified, and a qualification summary report for each is on file in the Mentor Library.	Yes
Attachment #7: Test Method Verification	All test methods necessary for the completion of this qualification have been verified and included.	Yes
Attachment #8: Shell Dipping Summary	All of the shell dipping normal production variance required by the protocol has been documented in the production shop orders. The shop orders have been summarized in this attachment.	Yes
Attachment #9: Sheeting Summary	All of the sheeting normal production variance required by the protocol has been documented in the production shop orders. The shop orders have been summarized in this attachment.	Yes
Attachment #10: Cut Parts/Texturing Summary	All of the cut parts/ texturing normal production variance required by the protocol has been documented in the production shop orders. The shop orders have been summarized in this attachment.	Yes
Attachment #11: Vulcanizer Verification	All vulcanizer parameters conform with all specifications before and after each trial run.	Yes

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**Table #2 (Continued)
 Process Qualification Results**

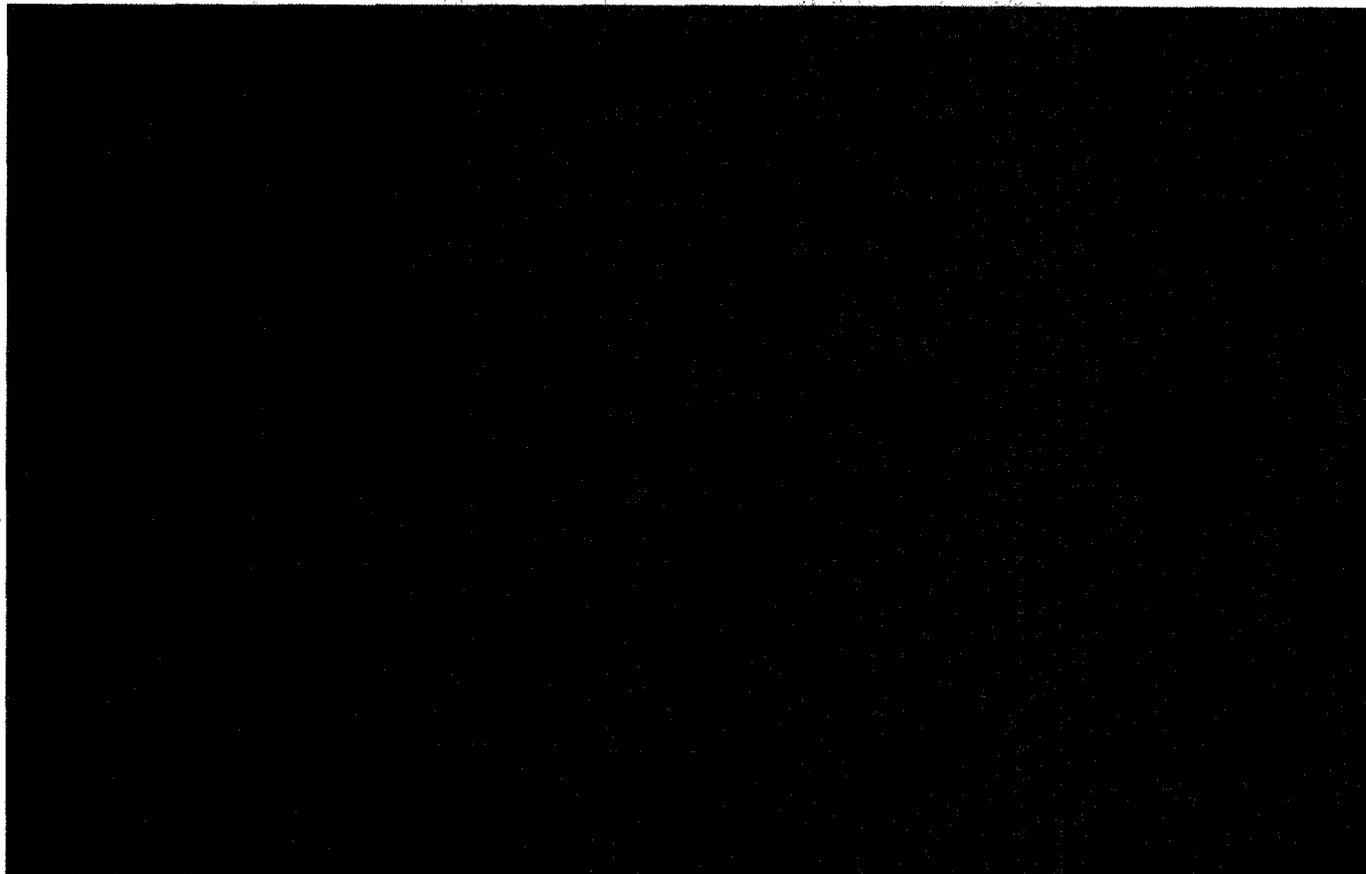
Protocol Attachments	Results	Conforms? (Yes/No)
Attachment #12: Process Challenge – Test Results Conformance	All calculations for normal/non-normal distribution have been completed and all data is attached. All data conforms to acceptance criteria.	Yes
Appendix #1: Requalification Requirements	Requalification requirements have been defined in accordance with Mentor Standard Operating Procedure SOP-HS-178.	Yes
Appendix #2: Protocol	A copy of Protocol HS33.980902.02, Rev 0, "Product Performance Qualification Protocol For the Siltex Moderate Profile Round Gel-Filled Mammary Prosthesis," has been included.	Yes
Appendix #3: Sample Size Calculations	Sample size calculations were performed after qualification testing for each lot to confirm that a sufficient number of samples were tested.	Yes
Appendix #4: Deviations	Deviation 1: 800cc devices were used for bioburden and LAL endotoxin testing rather than the 100cc devices specified in the protocol. Deviation 2: Additional red-lined information was added to PROC700852, PROC000185 and TM000337 for clarification. PROC 000218 was added to the documents red-lined. Deviation 3: Added Attachment #5 "Process Equipment Verification – Component Assembly" (inadvertently omitted) as page 31A. Deviation 4: Added additional page to the seal peel section of Attachment #12 to breakdown data into outer seal peel and inner seal peel. Deviation 5: Tables were added to document the acceptability of the Gel material lots used and the assembly lots in which they were used. Deviation 6: Table 1 of Redlined PROC000218 incorrectly specified oven capacity of 546 small thermoforms rather than 455. Deviation 7: Sections 8.8, 8.9 and 8.11 were improperly numbered in the protocol.	NA



6.0 SPECIFICATIONS AND ACCEPTANCE CRITERIA

The following table lists the tests, specifications, and acceptance criteria used for data analysis of protocol HS33.980902.02, "Product Performance Qualification Protocol for the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis".

Table #3
Specifications and Acceptance Criteria



If it was determined that the distribution for the trial was non-normal, the following was used to determine acceptability:

Table #4
Non-Normal Acceptance Criteria

Specification	Non-Normal Acceptance Criteria
Two sided limits	0.135 and 99.865 percentile values within spec.
One sided-low	0.135 percentile value \geq lower spec. limit
One sided-high	99.865 percentile value \leq upper spec. limit



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7.0 TEST RESULTS

The following table documents the results from the microbiological and physical testing of the trials run in protocol number HS33.980902.02, "Product Performance Qualification Protocol for the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis". Data and analysis can be found with Attachment 12, "Process - Test Results Conformance".

PYROGENICITY

All samples from Trials #2, #4 and #6 must have an endotoxin limit of ≤ 0.5 EU/ml.

Trial #	Result
Trial 2	Pass
Trial 4	Pass
Trial 6	Pass

BIOBURDEN

All samples from Trials #2, #4 and #6 must have an aerobic count of less than 455 colony forming units (CFU).

Trial #	CFU	Result
Trial 2	3 (max)	Pass
Trial 4	36 (max)	Pass
Trial 6	8 (max)	Pass

STERILITY CONFIRMATION

All samples must have no bacterial growth observed over a 7 day incubation period.

Trial #/Sterility Lot #	Bacterial Growth	Result
Trial 1/Sterility Lot #98228D	None	Pass
Trial 2/Sterility Lot #98228D	None	Pass
Trial 3/Sterility Lot #98232D	None	Pass
Trial 4/Sterility Lot #98232D	None	Pass
Trial 5/Sterility Lot #98236D	None	Pass
Trial 6/Sterility Lot #98236D	None	Pass



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INNER LID PACKAGING SEAL PEEL STRENGTH

The mean must be ± 3 standard deviations away from the 1.0 – 4.0 lb. specification (Normal Distribution) OR 0.135 and 99.865 percentile values within specifications. (Non-Normal Distribution).

Trial #	Distribution	Mean (lb.)	0.135 percentile	99.865 percentile	-3 standard deviations	+3 standard deviations	Result
Trial 1	Non-Normal	2.0	1.4	3.2	NA	NA	Pass
Trial 2	Normal	2.3	NA	NA	1.4	3.3	Pass
Trial 3	Non-Normal	2.1	1.6	3.1	NA	NA	Pass
Trial 4	Normal	2.2	NA	NA	1.3	3.2	Pass
Trial 5	Normal	1.9	NA	NA	1.2	2.7	Pass
Trial 6	Non-Normal	2.1	1.6	3.0	NA	NA	Pass

OUTER LID PACKAGING SEAL PEEL STRENGTH

The mean must be ± 3 standard deviations away from the 1.0 – 4.0 lb. specification (Normal Distribution) OR 0.135 and 99.865 percentile values within specifications. (Non-Normal Distribution).

Trial #	Distribution	Mean (lb.)	0.135 percentile	99.865 percentile	-3 standard deviations	+3 standard deviations	Result
Trial 1	Normal	1.9	NA	NA	1.2	2.6	Pass
Trial 2	Non-Normal	1.9	1.7	2.9	NA	NA	Pass
Trial 3	Non-Normal	2.0	1.5	3.1	NA	NA	Pass
Trial 4	Normal	2.1	NA	NA	1.2	3.0	Pass
Trial 5	Normal	1.8	NA	NA	1.2	2.4	Pass
Trial 6	Normal	1.9	NA	NA	1.1	2.7	Pass

GEL COHESION

All samples must pass pendant length ≤ 45 mm @ 30 minutes.

Trial #	200% elongation for 10 sec.
Trial 1	All samples Passed
Trial 2	All samples Passed
Trial 3	All samples Passed
Trial 4	All samples Passed
Trial 5	All samples Passed
Trial 6	All samples Passed



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TENSION SET

The mean must be at least three standard deviations away from the 10% maximum specification (Normal Distribution) OR the 99.865 percentile value must be \leq upper specification limit (Non-Normal Distribution).

Trial #	Distribution	Mean (%)	99.865 percentile	+ 3 standard deviations	Result
Trial 1	Normal	4	NA	5	Pass
Trial 2	Normal	3	NA	4	Pass
Trial 3	Normal	4	NA	4	Pass
Trial 4	Normal	3	NA	3	Pass
Trial 5	Non-Normal	3	3.922	NA	Pass
Trial 6	Normal	3	NA	3	Pass

SHELL / PATCH JOINT STRENGTH

All samples must pass 200% elongation for 10 sec

Trial #	200% elongation for 10 sec.
Trial 1	All samples Passed
Trial 2	All samples Passed
Trial 3	All samples Passed
Trial 4	All samples Passed
Trial 5	All samples Passed
Trial 6	All samples Passed

ELONGATION

The mean must be at least three standard deviations away from the 350% minimum specification (Normal Distribution) OR 0.135 percentile value must be \geq lower specification limit (Non-Normal).

Trial #	Distribution	Mean %
Trial 1	Normal	634
Trial 2	Normal	639 6394
Trial 3	Normal	578
Trial 4	Normal	615
Trial 5	Normal	569
Trial 6	Normal	504



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8.0 CONCLUSION

All Pyrogenicity, Bioburden, Sterility, Inner Packaging Seal Strength, Outer Packaging Seal Strength, Tension Set, Shell/Patch Joint Strength and Ultimate Elongation data pass the acceptance criteria as defined in Protocol HS33.980902.02, Rev 0. These results confirm that the Siltex® Moderate Profile Round Gel-Filled Mammary Prosthesis (fabricated according to nominal processing conditions defined in precedent process performance qualifications) meet the requirements defined in the aforementioned protocol.

9.0 REFERENCES

- 9.1 Mentor Standard Operating Procedure, SOP-HS-111 – “Process Validation.”
- 9.2 Mentor Standard Operating Procedure, SOP-HS-052 – “Product Performance Qualification.”
- 9.3 Mentor Standard Operating Procedure, SOP-HS-178 – “Requalification/Revalidation Requirements.”
- 9.4 Mentor Finished Device Specification, SPEC800008 – “Dry Heat Sterilized Siltex® Gel Filled Mammary Performance Specifications.”
- 9.5 HS33.980112.02 – “Process Qualification Summary Report for the HTV Moderate Profile Shell Dipping Process.”
- 9.6 HS72.980527.01 – “Process Qualification Summary Report for the Unvulcanized [REDACTED] Sheeting Manufacturing Process.”
- 9.7 HS72.980330.01 – “Process Qualification Summary Report for Vulcanized/Unvulcanized [REDACTED] Sheeting Manufacturing Process.”
- 9.8 HS33.980925.02 – “Process Qualification Summary Report for the Assembly of Siltex Moderate Profile Round Gel-Filled Mammary Prostheses.”
- 9.9 HS33.980612.01 – “Process Qualification Summary Report for Pre-sterilization Packaging.”
- 9.10 HS33.980612.02 – “Process Qualification Summary Report for Post-Sterilization Packaging.”
- 9.11 HS461.980331.02 - 1998 Truck Oven #2 Sterilization Process Requalification Summary Report for Mentor Corporation Irving, TX Facility
- 9.12 HS461.980630.01 – 1998 Truck Oven #3 Sterilization Process Requalification Summary Report for Mentor Corporation Irving, TX Facility
- 9.13 PROC000065 – “Pre-Mix Gel.”
- 9.14 PROC000105 – “Sampling of Sterile Products for Pyrogen Testing”



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- 9.15 PROC000185 – “Packaging of Product When Lidded Thermoforms are to be Used”
- 9.16 PROC000209 – “Barcode Verification Operator Guide.”
- 9.17 PROC000218 – “Dry Heat Sterilization Procedure.”
- 9.18 PROC000222 – “Preprocessing of Dimethyl and [REDACTED] Dispersion.”
- 9.19 PROC000248 – “Extruding and Screening Silicone Elastomers.”
- 9.20 PROC000249 – “Compounding of Silicone Elastomers.”
- 9.21 PROC000256 – “Cleaning of Silicone Gel Pump Systems and Filler”
- 9.22 PROC000259 [REDACTED]
- 9.23 PROC000261 – [REDACTED]
- 9.24 PROC000308 – “Dipping of Gel Shells.”
- 9.25 PROC500284 – [REDACTED]
- 9.26 PROC600852 – “Low Bleed Mammary Prosthesis Gel Filling and Curing.”
- 9.27 PROC700852 – “Packaging and Dry Heat Sterilization of Siltex Low Bleed Mammaries.”
- 9.28 QCIC000010 – “Packaged Products.”
- 9.29 QCIC000018 – “Silicone Sheeting.”
- 9.30 QCIC000114 – “Low Bleed Gel-Filled Mammaries & Sizers Inspection
- 9.31 QCIC600852 – “Siltex Low Bleed Gel-Filled Mammaries Inspection.”
- 9.32 TM000020 – “Toxicity Testing.”
- 9.27 TM000073 – “Determination of Bioburden on Products Prior to Sterilization”
- 9.28 TM000098 – “LAL Endotoxin Test”
- 9.33 TM000177 – “Peel Strength of Coated Lids.”
- 9.34 TM000337 – “Determination of Mechanical Performance of Shells, Patches and Joints in Gel-Filled Breast Prostheses.”
- 9.35 TM000366 – “ASTM Gel Cohesion Test Method.”
- 9.36 TM000384 – “Sterility Test Method.”
- 9.37 TM000405 – “Lap Shear Testing of Platinum Sheeting.”

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Appendix #1
Requalification Requirements

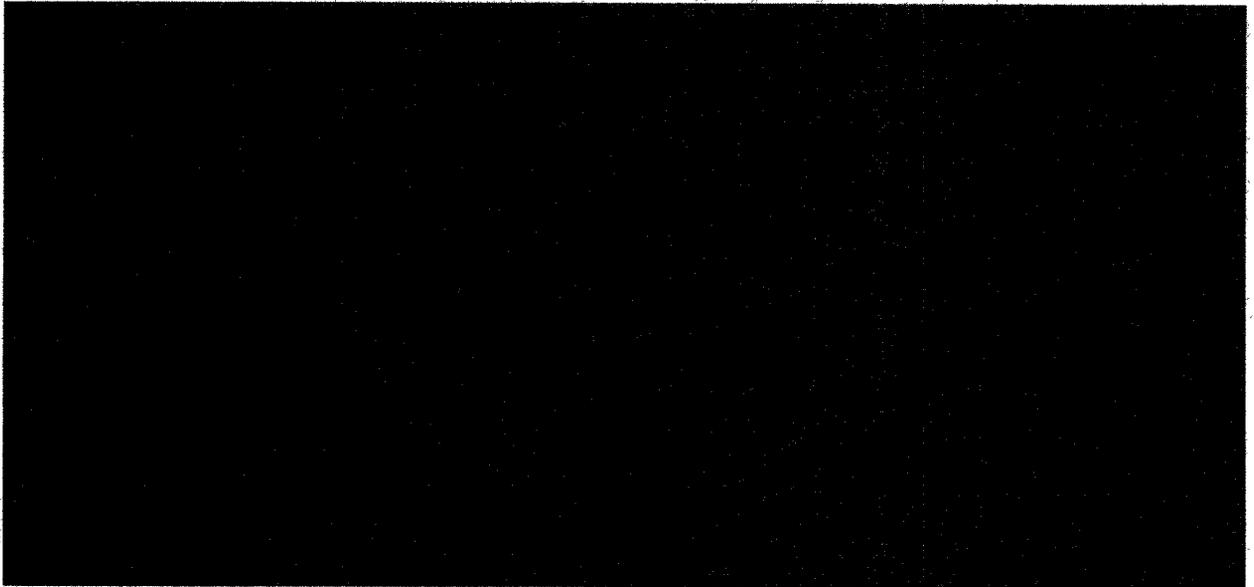
The following requalification requirements are considered the minimum requirements to be addressed in the event of a change to the product. The extent of requalification required will depend upon the nature of the change and its impact on the validation status with reference to this product performance qualification report in accordance with Mentor Standard Operating Procedure SOP-HS-178.

1. Unusual or atypical results seen during a product monitoring program.
 - 1.1 Product Monitoring

Current product monitoring consists of finished device testing on a lot by lot basis. The General Services and Microbiology Laboratories test in accordance with the test methods specified the product's finished device specifications (listed in the table below).

Finished device test data will continue to be collected and reviewed on an ongoing basis to verify that the product meets the stated specifications. Changes in the specifications will be evaluated for impact on the validation status of the product.

Finished Device Testing Specifications





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1.2 Each product family will be evaluated, at least annually, for conformance to its precedent finished device specification. If large variation is identified in the product monitoring results, as indicated in a change in the product's capability to meet its specifications, a formal review of the product's performance qualification will result. The review process, regardless of its outcome, will be formally documented and retained for reference.

2. Change in product specifications or quality characteristics.

A change in the product specifications or quality characteristics will require requalification evaluation for impact to validated status. The product specifications are listed in section 1 above.

3. Change in the standard production lot size.

3.1 The standard production lot sizes are [REDACTED] devices. A change in the standard production lot size to [REDACTED] devices will be evaluated for impact on the validation status.

3.2 A change in the method of dry heat sterilization oven loading will be evaluated for impact on the validation status.

4. Change in the definition of the product family, including the addition of new sizes and/or line extension.

A change in the definition of the product family, including the addition of new sizes and/or a line extension, will require requalification equivalent to the requirements specified in protocol HS33.980902.02, Rev. 0.



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Siltex® Moderate Profile Round Gel-Filled Mammary Prostheses
Moderate Profile - Style 7000

Catalog Number	Volume (cc)
354-1007	100
354-1257	125
354-1507	150
354-1757	175
354-2007	200
354-2257	225
354-2507	250
354-2757	275
354-3007	300
354-3257	325
354-3507	350
354-3757	375
354-4007	400
354-4507	450
354-5007	500
354-5507	550
354-6007	600
354-7007	700
354-8007	800

5. Non-equivalent change in the processes used to manufacture the product.

A non-equivalent change in any of the parameters, tooling, components, or raw materials in any of the processes used to manufacture the product will require requalification evaluation for impact to validated status.

Impact of non-equivalent changes to any of the following process qualification summary reports must be addressed. The current revision of the report (the report in effect on the date of review) shall be used.

- HS33.980112.02 – “Process Qualification Summary Report for the HTV Moderate Profile Shell Dipping Process.”
- HS72.980527.01 – “Process Qualification Summary Report for the Unvulcanized [REDACTED] Sheeting Manufacturing Process.”
- HS72.980330.01 – “Process Qualification Summary Report for Vulcanized/Unvulcanized [REDACTED] Sheeting Manufacturing Process.”

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- HS33.980925.02 – “Process Qualification Summary Report for the Assembly of Siltex Moderate Profile Round Gel-Filled Mammary Prostheses.”
- HS33.980612.01 – “Process Qualification Summary Report for Packaging of [REDACTED] Thermoforms (Pre-sterilization).”
- HS33.980612.02 – “Process Qualification Summary Report for Post-Sterilization Packaging.”
- HS33.980612.02 – “Process Qualification Summary Report for Sterility Shelf Life and Shipping integrity of [REDACTED] Thermoforms and Accessory Pouches.”
- HS461.980331.02 – “1998 Truck Oven #2 Sterilization Process Requalification Summary Report for Mentor Corporation Irving, TX Facility.”
- HS461.980630.01 – 1998 Truck Oven #3 Sterilization Process Requalification Summary Report for Mentor Corporation Irving, TX Facility