

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802		DATE(S) OF INSPECTION 8/19/2025-8/28/2025* FEI NUMBER 1000307504	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jill Grandas, Corporate Executive Director			
FIRM NAME DCI Donor Services, Inc.		STREET ADDRESS 566 Mainstream Drive, Suite 300	
CITY, STATE, ZIP CODE, COUNTRY Nashville, TN 37228-1234		TYPE ESTABLISHMENT INSPECTED Human Tissue Processor	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.			
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Donors were not determined to be ineligible that had risk factors or clinical evidence of communicable disease agents. Specifically, in (b) (4) of the (b) (4) donor charts we reviewed for 2024-2025, donors with documentation of a (b) (4) where this condition was not ruled out were determined eligible by the Medical Director. - The hospital medical records available at your firm for Donor (b) (6), (b) (7)(C) showed the donor was diagnosed with (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) Your firm recovered musculoskeletal tissues for this donor on (b) (6), (b) (7)(C), determined this donor eligible on 10/10/2024, and distributed these tissues for transplantation on 08/13/2025. - The hospital medical records available at your firm for Donor (b) (6), (b) (7)(C) showed the donor was diagnosed with (b) (6), (b) (7)(C) Your firm recovered musculoskeletal tissues for this donor on (b) (6), (b) (7)(C), determined this donor eligible on 02/18/2025, and distributed these tissues for transplantation on 08/13/2025.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Christopher J Adams, Investigator Jannet M Peroti, Investigator Fabian N Chaparro-Rodriguez, Investigator Fabian N Chaparro-Rodriguez, Investigator Signed by: Fabian N. Chaparro-Rodriguez - 08 Date Signed: 08-28-2025 11:32:13 	
		DATE ISSUED 8/28/2025	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802		DATE(S) OF INSPECTION 8/19/2025-8/28/2025* FEI NUMBER 1000307504	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jill Grandas, Corporate Executive Director			
FIRM NAME DCI Donor Services, Inc.		STREET ADDRESS 566 Mainstream Drive, Suite 300	
CITY, STATE, ZIP CODE, COUNTRY Nashville, TN 37228-1234		TYPE ESTABLISHMENT INSPECTED Human Tissue Processor	
- The hospital medical records available at your firm for Donor (b) (6), (b) (7)(C) showed the donor was diagnosed with (b) (6), (b) (7)(C) Your firm recovered musculoskeletal tissues for this donor on (b) (6), (b) (7)(C), determined this donor eligible on 01/31/2024, and distributed these tissues for transplantation on 08/13/2025. - The hospital medical records available at your firm for Donor (b) (6), (b) (7)(C) showed the donor was diagnosed with (b) (6), (b) (7)(C) Your firm recovered musculoskeletal tissues for this donor on (b) (6), (b) (7)(C), determined this donor eligible on 04/19/2024, and distributed these tissues for transplantation on 08/13/2025 and 08/15/2025. - The hospital medical records available at your firm for Donor (b) (6), (b) (7)(C) showed the donor was diagnosed with (b) (6), (b) (7)(C) Your firm recovered musculoskeletal tissues for this donor on (b) (6), (b) (7)(C), determined this donor eligible on 03/22/2024, and distributed these tissues for transplantation on 08/13/2025.			
OBSERVATION 2 Facilities were not maintained in a good state of repair. Specifically, During a walkthrough of your cleanroom processing areas on 08/20/2025, we observed chipping, missing, and deteriorated paint on the ceiling molding throughout your cleanrooms as well as on (b) (4) (b) (4) and framing around light fixtures located within your tissue processing rooms. Representative			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Christopher J Adams, Investigator Jannet M Peroti, Investigator Fabian N Chaparro-Rodriguez, Investigator Fabian N Chaparro-Rodriguez, Investigator Signed by: Fabian N. Chaparro-Rodriguez - 45 Date Signed: 08-28-2025 11:32:13 	
		DATE ISSUED 8/28/2025	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

404 BNA Dr., Bldg. 200, Ste. 500
Nashville, TN 37217-2597
(615) 366-7801 Fax: (615) 366-7802

DATE(S) OF INSPECTION

8/19/2025-8/28/2025*

FEI NUMBER

1000307504

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Jill Grandas, Corporate Executive Director

FIRM NAME

DCI Donor Services, Inc.

STREET ADDRESS

566 Mainstream Drive, Suite 300

CITY, STATE, ZIP CODE, COUNTRY

Nashville, TN 37228-1234

TYPE ESTABLISHMENT INSPECTED

Human Tissue Processor

examples of locations where this was observed include:

Room Number

Classification

Room Function

(b) (4)

ISO-(b) (4)

(b) (4)

(b) (4)

ISO-(b) (4)

(b) (4)

(b) (4)

ISO-(b) (4)

(b) (4)

(b) (4)

ISO-(b) (4)

(b) (4)

(b) (4)

ISO-(b) (4)

(b) (4)

(b) (4)

ISO-(b) (4)

(b) (4)

(b) (4)

ISO-(b) (4)

(b) (4)

(b) (4)

ISO-(b) (4)

(b) (4)

OBSERVATION 3

Equipment used for manufacturing HCT/Ps was not cleaned according to established schedules.

Specifically,

Your firm uses (b) (4) for the (b) (4) of musculoskeletal tissue products. During a walkthrough of your facility on 08-20-2025 we observed apparent tissue residue "crumbs" inside the

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Christopher J Adams, Investigator
Jannet M Peroti, Investigator
Fabian N Chaparro-Rodriguez, Investigator

Fabian N Chaparro-Rodriguez
Investigator
Signed By: Fabian N. Chaparro-
Rodriguez-08
Date Signed: 08-28-2025
11:32:13

X

DATE ISSUED

8/28/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

404 BNA Dr., Bldg. 200, Ste. 500
Nashville, TN 37217-2597
(615) 366-7801 Fax: (615) 366-7802

DATE(S) OF INSPECTION

8/19/2025-8/28/2025*

FEI NUMBER

1000307504

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Jill Grandas, Corporate Executive Director

FIRM NAME

DCI Donor Services, Inc.

STREET ADDRESS

566 Mainstream Drive, Suite 300

CITY, STATE, ZIP CODE, COUNTRY

Nashville, TN 37228-1234

TYPE ESTABLISHMENT INSPECTED

Human Tissue Processor

(b) (4) below and adjacent to the (b) (4) where in-process material is held during processing. Two of these (b) (4) were noted to be in use, and two were documented as having been cleaned.

***DATES OF INSPECTION**

8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri), 8/25/2025(Mon), 8/26/2025(Tue), 8/27/2025(Wed), 8/28/2025(Thu)

X Jannet M Peroti
Investigator
Signed By: JANNET M. PEROTI-S
Date Signed: 08-28-2025 11:32:57

X Christopher J Adams
Investigator
Signed By: Christopher J. Adams -S
Date Signed: 08-28-2025 11:33:32

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Christopher J Adams, Investigator
Jannet M Peroti, Investigator
Fabian N Chaparro-Rodriguez, Investigator

X Fabian N Chaparro-Rodriguez
Investigator
Signed By: Fabian N. Chaparro-
Rodriguez -S
Date Signed: 08-28-2025
11:32:13

DATE ISSUED

8/28/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."