

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768		DATE(S) OF INSPECTION 2/18/2025-2/26/2025*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dr. Bruce R. Werber, CEO / Founder		FEI NUMBER 3027649380	
FIRM NAME BioXtek LLC	STREET ADDRESS 316 NE 1st St		
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33060-6608	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 I OBSERVED: OBSERVATION 1 Processes with results which could not be fully verified by inspection and tests, were not validated and approved according to established procedures. Specifically, Since you began manufacturing on 5/11/2023 until 11/24/2024, you manufactured and distributed (b) (4) amniotic membrane grafts without conducting a validation of your process. Process Validation (VP-002) for the membrane product family: Single Amniotic Membrane (SAM), Dual Amniotic Membrane (DAM), and Optical Product was not conducted until 11/24/2024.			
OBSERVATION 2 Process changes were not verified to ensure the change does not cause an adverse impact elsewhere in operations. Specifically, Since conducting your process validation on 11/24/2024, you manufactured Lyophilized Amnio Matrix products for your customer using an alternative process. You manufactured and distributed (b) (4) lyophilized amniotic membrane grafts between October and December 2024, using a lyophilization step that was not included in your validated process. After the release of the product, you conducted a Risk Analysis on 2/6/2025.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ivan E Reyes, Investigator		DATE ISSUED 2/26/2025
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Ivan E Reyes, Investigator Signed By: 2000357185 Date Signed: 02-26-2025 15:19:09 X	DATE ISSUED 2/26/2025

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

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Maitland, FL 32751
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DATE(S) OF INSPECTION

2/18/2025-2/26/2025*

FEI NUMBER

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Bruce R. Werber, CEO / Founder

FIRM NAME

BioXtek LLC

STREET ADDRESS

316 NE 1st St

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Pompano Beach, FL 33060-6608

TYPE ESTABLISHMENT INSPECTED

Human Tissue Processor

OBSERVATION 3

Donors were not tested for evidence of infection with relevant communicable disease agents.

Specifically,

Birth tissue from donor (b) (4), (b) (6), (b) (7)(C) was recovered on (b) (6), (b) (7)(C) and was not tested for West Nile Virus (WNV NAT). Your (b) (4), (b) (6), (b) (7)(C) Associate, deemed this donor eligible on 8/29/2023.

Tissue from this donor was processed in (b) (4), (b) (6), (b) (7)(C) resulting into (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C) Subsequently, these grafts were released for distribution on 9/12/2023.

***DATES OF INSPECTION**

2/18/2025(Tue), 2/19/2025(Wed), 2/20/2025(Thu), 2/24/2025(Mon), 2/26/2025(Wed)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Ivan E Reyes, Investigator

Ivan E Reyes
Investigator
Signed By: 2000357185
Date Signed: 02-26-2025
15:19:09

X

DATE ISSUED

2/26/2025

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."