

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

DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160	DATE(S) OF INSPECTION 9/8/2025-9/12/2025 FEI NUMBER 3003828812
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daehee Moon, Tissue Bank President

FIRM NAME Hans Biomed Corporation	STREET ADDRESS 64 Yuseong-Daero 1628 Beon-Gil
CITY, STATE, ZIP CODE, COUNTRY Youseong-gu, DAEJEON, 34054 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED 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

Records were not accurate.

Specifically, the (b) (4) for Donor ID: (b) (4), (b) (5), (b) (7) and Batch No. (b) (4), states the following on Page 2, Step (b) (4):

(b) (4)

It also notes: (b) (4)

The documented total working time for Step (b) (4) is (b) (4) on 09/09/25, and the freezer storage time is listed as (b) (4) on 09/09/25.

However, on 09/11/25, I was informed that the (b) (4) was used (b) (4) from the freezer at (b) (4) on 09/09/25, just (b) (4) Step (b) (4). The batch record documents Step (b) (4) as completed between (b) (4) on 09/09/25. I was present during that time and did not observe use of the (b) (4).

Since the (b) (4) is part of Step (b) (4), the completion time for Step (b) (4) should occur (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Amy Kim, Investigator	Amy Kim Investigator Signed By: 2000481080 Date Signed: 09-12-2025 00:35:23 X	DATE ISSUED 9/12/2025

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Daehee Moon, Tissue Bank President
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(b) (4) - therefore, it must be (b) (4) as currently documented.

Additionally, cleaning records for the (b) (4) and (b) (4) (referenced in Step (b) (4) and Step (b) (4) of other batch records) were reviewed and found to be inconsistent for the dates of use. For example:

- The (b) (4) (Batch No. (b) (4), Donor ID (b) (4), (b) (6), (b) (7), Unprocessed Material No. (b) (4)) references (b) (4) Equipment No. (b) (4) and (b) (4) Cleaning Record No. (b) (4) in Step (b) (4), dated 04/21/25 (page 3). However, the corresponding (b) (4) Cleaning Record lists the same record number ((b) (4)), but the cleaning was performed on 04/17/25 for a different unprocessed material number ((b) (4)).
- The (b) (4) (Batch No. (b) (4), Donor ID (b) (4), (b) (6), (b) (7), Unprocessed Material No. (b) (4)) references (b) (4) Equipment No. (b) (4) and (b) (4) Cleaning Record No. (b) (4) in Step (b) (4), dated 06/24-26/24 (page 2). The corresponding (b) (4) Cleaning Record is documented as (b) (4) (b) (4). While the equipment number ((b) (4)) and cleaning date (06/24/24) are correctly documented, the cleaning record number listed in the batch record does not match the number recorded on the (b) (4) Cleaning Record.
- The (b) (4) (Batch No. (b) (4), Donor ID (b) (4), (b) (6), (b) (7)) lists (b) (4) (b) (4) Cleaning Record No. (b) (4), but the corresponding cleaning record documents the Donor ID as (b) (4), (b) (6), (b) (7)(C) and the cleaning record number as (b) (4). This indicates discrepancies in both donor ID and cleaning record number formatting between the batch record and cleaning record.

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Daehee Moon, Tissue Bank President

FIRM NAME

Hans Biomed Corporation

STREET ADDRESS

64 Yuseong-Daero 1628 Beon-Gil

CITY, STATE, ZIP CODE, COUNTRY

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Republic of)

TYPE ESTABLISHMENT INSPECTED

Tissue Processor

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Amy Kim, Investigator

Amy Kim
Investigator
Signed By: 2000481080
Date Signed: 09-12-2025
00:35:23

X

DATE ISSUED

9/12/2025

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."