DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	7/28/2025-7/31/2025
	FEI NUMBER 3007697975

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alicia Robert-Laschette, Export Sales Coordinator

FIRM NAME	STREET ADDRESS
Euromi S.A.	Rue Des Nouvelles Technologies, 11, ZI Des Plenesses
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Andrimont, Liege, 4821 Belgium	Medical Device Manufacturer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, the firm's Non-Conformities – Corrective and Preventive Actions Procedure, Document #P7-F.V12, is inadequate in that:

- the procedure is used to document individual non-conformities found during audits and manufacturing.

- the procedure is also being used as an extension to the complaint handling system for addressing corrections.

OBSERVATION 2

Procedures for acceptance activities have not been established.

Specifically, once the EVA sp6 Lipoplasty Suction System is assembled, the unit needs to be inspected and approved (as indicated in the DHR as Assembly Control). However, the firm has yet to establish and maintain acceptance procedures for the EVA sp6 Lipoplasty Suction System.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Thai T Duong, Investigator X Thai T Duong Investigator Signed By: 1300092605 Date Signed: 07-31-2025 07:29:16	7/31/2025

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CITY, STATE, ZIP CODE, COUNTRY Andrimont, Liege, 4821 Belgium	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

OBSERVATION 3

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

Specifically, the firm's manufacturing procedures/working instructions of the EVA sp6 Lipoplasty Suction System are incomplete in that the procedures/working instructions require the following:

(b)(4)

However, the technicians are not documenting any of the above assembly/calibration steps in the production record (showing that they were performed).

For example: DHRs for Serial # (b)(4) and Serial # (b)(4)

OBSERVATION 4

MDR event files have not been established and maintained.

Specifically, the firm fails to establish and maintain MDR event files. They have submitted a total of five MDRs from 2023 to 2025 and none were available for review during the inspection.

OBSERVATION 5

The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided.

Specifically, firm fails to provide required information to Global Unique Device Identification Database (GUDID) pursuant to 21 CFR 830.300. For example:

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-Non-sterile Liposuction Equipment – Eva sp6
-Pneumatic Handpiece Evamatic 5

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

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X Thai T Duong
Investigator
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07:29:16

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7/31/2025

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."