

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

10903 New Hampshire Avenue
Silver Spring, M.D. 20993
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<http://www.fda.gov>

DATE(S) OF INSPECTION

10/20/2025-10/24/2025

FEI NUMBER

3015217460

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Ramon N. Farrugia, Chief Operating Officer

FIRM NAME

Implantica CE Reflux Limited

STREET ADDRESS

Malta Life Sciences Park, Level 0
Sir Temi Zammit Buildings

CITY, STATE, ZIP CODE, COUNTRY

San Gwann, SGN3000, Malta

TYPE ESTABLISHMENT INSPECTED

Bioresearch Sponsor, 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically, the following deficiencies were found in these CAPA records:

CAPA 00001: Inadequate Corrective Actions (ineffective training) and Effectiveness Check Plan (no interim checks)

CAPA 00003: Inadequate Effectiveness verification plan for systemic QMS issue (no interim checks)

CAPA 00002:

1. Investigation – Missing Process-Parameter Documentation

The investigation does not contain any documented evidence that the (b)(4) tumbler was the equipment actually used throughout production. There is no record showing that the speed, rpm, and other parameters employed on the RS-300 devices match the values specified in the original validation reports (IQ/OQ/PQ).

2. Corrective Action – Incomplete Batch-Record Amendment

The corrective-action portion of the CAPA fails to provide documented proof that all affected batch records, including previously released batch records (job-router forms, batch-release sheets, and any downstream documentation) have been updated to include the tumbler model-number (e.g., (b)(4) as the equipment used for the tumbling operation.

3. Scope & Preventive Action – Insufficient Coverage

The CAPA scope is limited to the single subcontractor (b)(4) and the one batch in question. The scope should be expanded to verify that the same omission (absence of equipment identification) does not exist in any other batch-record packages, whether they involve the same tumbler or other subcontractors, and appropriate preventive actions should be instituted to prevent recurrence.

**SEE REVERSE
OF THIS PAGE**

John Sciacchitano, Investigator
Kathryn Suttling, Investigator
Lakecha N. Lewis, Investigator

John
Sciacchitano -S
KATHRYN L.
SUTTTLING -S

Digitally signed by John
Sciacchitano -S
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Date: 2025.10.24 13:33:47
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Lakecha N. Lewis
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Lewis -S
Date: 2025.10.24 13:35:16 +02'00'

DATE ISSUED

10/24/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, M.D. 20993 +1-301-796-5653 http://www.fda.gov		DATE(S) OF INSPECTION 10/20/2025-10/24/2025	
		FEI NUMBER 3015217460	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ramon N. Farrugia, Chief Operating Officer			
FIRM NAME Implantica CE Reflux Limited		STREET ADDRESS Malta Life Sciences Park, Level 0 Sir Temi Zammit Buildings	
CITY, STATE, ZIP CODE, COUNTRY San Gwann, SGN3000, Malta		TYPE ESTABLISHMENT INSPECTED Bioresearch Sponsor, Manufacturer	
<p>OBSERVATION 2</p> <p>Procedures to ensure that sampling methods are adequate for their intended use have not been adequately established.</p> <p>Specifically, the firm's procedures for establishing sample sizes in validation activities lack clear guidance on when an external standard (such as an ANSI/ISO sampling requirement) can override or replace the organization's own internal criteria. The procedures do not specify the necessary elements such as acceptance criteria, justification, rationale, approval process, methodology, or how to resolve any conflict between the two sources. Consequently, the choice of sample size in validation studies may be unsupported by statistical justification and applied inconsistently.</p> <p>For example: A sample size of six was initially selected in Protocol (DT_DVP0007 01) Manual Cleaning Validation Plan on the suggestion as per ANSI/AAMI ST98: 2022 [9]. ANSI/AAMI ST98: 2022 . This sample size was changed to 9, a more conservative sample size, as reflected in the validation report DT_DVR0007 03 Manual Cleaning Validation Report. Collectively, these validation reports did not adequately document the following:</p> <ul style="list-style-type: none"> the factors considered when selecting the initial six-unit size (expert judgment, industry practice, risk assessment, etc.). the rationale or explanation why a sample size of 9 was sufficient, even if recommended by the standard that could include a clear, risk-based rationale for the sample size used, is sufficient for the specific device, process and risk level, and explain the deviation from your own internal SOP. <p>OBSERVATION 3</p> <p>The organizational structure has not been adequately established and maintained to ensure that devices are manufactured in accordance with 21 CFR Part 820.</p> <p>Specifically, between approximately December 2024 and September 2025, the firm's approach to managing the quality system was, in part, triage-oriented rather than maintaining normal quality system operations. The departure of several key staff members resulted in delays and partial interruptions in the processing of CAPAs, change requests, nonconformances, and quality plans.</p> <p>OBSERVATION 4</p> <p>Process validation activities have not been adequately documented.</p> <p>Specifically, the stated purpose of the validation protocol (test instructions) RS DVP0004 "RefluxStop Radiopacity and Barium Sulphate," was not congruent with the conclusions in the corresponding output report RS DVR0004. The protocol documentation was inaccurate.</p>			
SEE REVERSE OF THIS PAGE	John Sciacchitano, Investigator	John Sciacchitano -S Date: 2025.10.24 13:31:53 +02'00'	DATE ISSUED 10/24/2025
	Kathryn Suttling, Investigator	KATHRYN L. SUTTLING -S Date: 2025.10.24 13:33:08 +02'00'	
	Lakecha N. Lewis, Investigator	Lakecha N. Lewis -S Date: 2025.10.24 13:35:56 +02'00'	
<div> <div>FORM FDA 483 (09/08)</div> <div>PREVIOUS EDITION OBSOLETE</div> <div>INSPECTIONAL OBSERVATIONS</div> <div>PAGE 2 of 2</div> </div>			

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."