

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715		DATE(S) OF INSPECTION 7/14/2025-7/17/2025 FEI NUMBER 3009173317	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Edward Kenny, Managing Director			
FIRM NAME Caragh Precision		STREET ADDRESS Parkmore Business Park West	
CITY, STATE, ZIP CODE, COUNTRY Galway, Co. GALWAY, H91 CH05 Ireland		TYPE ESTABLISHMENT INSPECTED 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.			
<i>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.</i>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Requirements that must be met by suppliers, contractors and consultants have not been adequately established. Specifically, PP 2 – Supplier Assessment for Medical Device Manufacture, rev 29, dated 11/07/2025 (previous revisions: rev 28 (dated 11/06/2025), and rev 27 (dated 17/01/2024)), does not ensure that all suppliers are adequately monitored by your firm. For example, A) The suppliers chosen for your firm’s quarterly supplier monitoring is based on monetary value instead of services and/or materials provided. Suppliers are not evaluated in a consistent manner even if they provide the same service and/or materials. For example, your firm’s AVL has 7 suppliers of Titanium 6Al-4V ELI Alloy that can be used in the manufacturing of your customer’s spinal rods. 5 out of the 7 suppliers are not included in the quarterly supplier monitoring. B) According to your supplier assessment procedure the failure of supplier to “adequately respond to corrective actions or multiple recurrences of the same non-conformances will result in their approval status being down graded or withdrawn”. Your assessment processes do not ensure that all CAPAs associated with suppliers are considered. For			
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Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich Date Signed: 07-17-2025 133430		X	

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example, a CAPA (number 1863) found that the root cause was possibly due a supplier related issue and was not included as part of the annual review for the supplier.			
OBSERVATION 2 Procedures for changes to a process and procedure have not been adequately established. Specifically, QP 5, "Change Control", rev 39, dated 11/07/2025 (previous revision, rev 38 (dated 12/12/2024)) does not ensure that all changes are adequately documented and controlled. For example, DCN Number 9433, dated 12JUN2025, was initiated to update the procedure for (b)(4) Monitoring (SOP363) from rev 16 to rev 17. As part of the procedure update, a change was made to the software programing associated with the Portable Particle Counter. This program change has not been documented.			
OBSERVATION 3 Procedures for corrective and preventive action have not been adequately established. Specifically, QP 22 "Corrective and Preventive Action" rev 14, dated 11/07/2025, (previous revisions: rev 13 (dated 27/11/2023), rev 12 (dated 29/06/2023), and rev 11 (dated 20/05/2021)), does not ensure that all CAPAs initiated by your firm are adequately verified for effectiveness. For example, Five (5) out of 11 CAPAs reviewed did not have an adequate verification of effectiveness prior to closure. Including the following CAPAs: - CAPA 1871, dated 26/05/2025, for "Testing/Air Sampling Results OOS - CAPA 1865, dated 18/03/2025, for Testing/TVC Results OOS - CAPA 1863, dated 25/02/2025, for Testing /Air Sampling Results OOS - CAPA 1775, dated 15/12/2023, for Training and			
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CAPA 1704, dated 07/02/2023, for Product not set up in GSS correctly.			
SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE Rosanna M Goodrich, Medical Device Specialist X Rosanna M Goodrich Medical Device Specialist Signed By: Rosanna M. Goodrich Date Signed: 07-17-2025 133430 DATE ISSUED 7/17/2025			
FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	
INSPECTIONAL OBSERVATIONS		PAGE 3 of 4 PAGES	

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Annotations to Observations Observation 1: Promised to correct Observation 2: Promised to correct Observation 3: Promised to correct			
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 4 of 4 PAGES			

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."