DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	5/6/2026-6/3/2026* FEI NUMBER 3022699058

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marcus J. Gesner, Vice President, Quality

FIRM NAME	STREET ADDRESS
embecta Medical II LLC	300 Kimball Drive Suite 300
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Parsippany, NJ 07054	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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Design and development validation was not adequately completed prior to release for use of the product to the customer.

Specifically, your firm failed to adequately implement *CP50006 Design Validation*, Revs 13-21, Eff. 03/10/2014 – 04/07/2026, and *CP50087 Human Factors and Useability Engineering Process*, Revs 1-11, Eff. 11/02/2017 – 04/07/2026, in that the (b) (4) , and (b) (4) products did not have their designs adequately validated before release. Review of your firm's design validation activities revealed they did not adequately include representative study populations or establish acceptance criteria which will adequately validate the design and intended use of the devices. Examples include but are not limited to:

1. The study populations do not include patients who are new users, children, (b) (4) who are not (b) (4) , visually impaired, or caregivers who are not healthcare professionals.
2. The studies do not adequately establish acceptance criteria relating to the useability of the device. Examples of requirements from the design traceability matrix which were not validated adequately include:
   - 2.A. "Device shall provide dose accuracy for compatible (b) (4) systems for the (b) (4) of drugs, including (b) (4)".
   - 2.B. "Device shall be compatible with (b) (4) systems marketed in specific regions for the (b) (4) of drugs, including (b) (4)"
   - 2.C. "Device shall provide safe (b) (4) from compatible (b) (4) systems after use"

Your firm has sold approximately (b) (4) and (b) (4)

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(b) (4) between 04/01/2024 and 05/06/2026 to US customers.

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, your firm failed to adequately implement *CP92021 US Adverse Event*, Revs 1-3, eff. 03/23/2023 – 11/02/2025, *CP92009 Adverse Event Reporting Policy*, Revs 1 – 6, Eff. 09/13/2022 – 01/16/2026, and *CP62096 Complaints Management and Adverse Event Reporting*, Revs 1 – 10, Eff. 04/04/2022 – 09/09/2025, in that your firm failed to submit MDR reports in instances where information suggests a marketed device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction were to recur. For example,

1. Complaint intake number 007800 received on 02/18/2026, led to complaint report 0011855, in which the event description states "During interviews with the (b) (4) department, about 3 patients have been reported that (b) (4) break easily***". Your firm submitted an MDR report on 03/12/2026 for this event. No follow up communications regarding this complaint were documented in the complaint report to determine information on the 3 patients and no additional MDR reports were submitted to capture the 3 events.

2. Complaint intake 008145, received on 03/24/2026, led to complaint reports 0012404, and 12405, the event description for these complaint reports state "Consumer Reported (b) (4) from this box. Different days. both (b) (4) broke off (b) (4) . 1 from last night 03.23.2026 she was able to (b) (4) on her own. The other (b) (4) break was about 2 weeks ago. Not sure if it fell to the floor after (b) (4) or it is still (b) (4) ***".

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Your firm submitted an MDR report on 04/21/2026 but did not submit an additional MDR report for the other instance which occurred.

3. Complaint intake 007838, received on 02/24/2026, led to complaint reports 0011899 and 0011900, the event description for these complaint reports state "***FOUR DIFFERENT PEOPLE HAVE SHARED THE (b) (4) HAS BROKEN OFF UPON/DURING (b) (4) THIS HAS STARTED TO HAPPEN WITH THE CHANGE THIS HAS ONLY OCCURRED WITH THE (b) (4) SINCE THE REPACKAGING OF THE NEW (b) (4) (COMPLAINTS IN THE LAST 3-6 WEEKS)***". Your firm submitted an MDR report on 03/25/2026 for this complaint, no information regarding attempts to collect more information regarding the 4 people was recorded in the complaint records, and no additional MDRs were submitted to capture the 4 people who appeared to have complained.

4. Complaint intake 007997, received on 03/10/2026, led to complaint report 0012136, which states in the event description "***I have received numerous complaints from clinical staff that the (b) (4) on the back end of the device is (b) (4), leading to the (b) (4) from the device which leaves the (b) (4) ***". Your firm submitted an MDR report on 04/08/2026 for this complaint. No information regarding attempts to collect more information regarding the potential several complaints was recorded on the complaint record. No additional MDRs were submitted.

5. Complaint intake 005147, received on 05/29/2025, led to complaint record 0007663. The event description of the complaint record states "I am reaching out to express concern regarding the quality of a recent batch of (b) (4) we purchased, which we regularly use for (b) (4) in out medical practice *** Several of out patients have reported increased pain during their (b) (4) treatments *** Upon inspection, it appears that the (b) (4) may be (b) (4) **". An MDR report was submitted by your firm on 06/26/2025, with a follow up submitted on 09/03/2025. No

information regarding attempts to collect more information regarding the potential several complaints was recorded on the complaint record. No additional MDRs were submitted.

6. Complaint intake 006445, received on 10/15/2025, led to complaint record 0009742. The complaint record's event description states "(b) (4) pain during (b) (4) *** Product is being used "off label" (b) (4) ** when she (b) (4) to some of her patients, they are complaining about "(b) (4) pain" *** DR stated in the past she's never heard these complaints from her patients it's only since the branding change ***". Your firm submitted an MDR report on 11/07/2025. No information regarding attempts to collect more information regarding the potential several complaints was recorded on the complaint record. No additional MDRs were submitted.

OBSERVATION 3

Controls over outsourced processes that affect product conformity to requirements are not proportionate to the risk involved.

Specifically, your firm failed to adequately implement *CP62088 Management of Outsourced* Process, Revs 1-4, Eff. 04/04/2022 – 07/14/2025, *CP62170 Quality Agreement Between emebcta Entities,* Revs 1 – 5, Eff. 09/02/2022 – 03/04/2026, *CP60109 Supplier Management Procedure*, Revs 22 – 30, Eff. 04/26/2022 – 04/22/2026, and *CP62004 Supplier Quality Risk Classification,* Revs 1 – 11, Eff. 04/04/2022 – 04/22/2026, in that your firm failed to adequately establish controls over suppliers responsible for the manufacturing of medical devices. Your firm outsources all manufacturing activities for products bearing your firm's name. Your firm failed to establish controls for the review and approval of batch records before release of finished product, controls to ensure suppliers will abide by corporate level procedures, and controls for the review and approval of all process validations conducted by the suppliers. Notably,

1)Your firm did not implement controls to ensure that your manufacturing site would produce Class II

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(b) (4) which meet (b) (4) specifications for the (b) (4). Specifically, your firm failed to adequately review and approve packaging process validations *V20-05-001* (b) (4), Rev. 1, Eff. 02/18/2020, and *V18-05-001 Line* (b) (4), Rev 1, Eff. 12/21/2017, conducted by a manufacturing site. The process validations conducted by the manufacturing site fail to adequately evaluate the ability of the equipment to (b) (4) products according to the design specifications across normal production. Your firm has sold approximately (b) (4) (b) (4) to US based customers between 04/01/2024 and 05/22/2026.

2)Your firm has not implemented controls to ensure batch records created at your manufacturing sites are reviewed and approved by embecta Medical II LLC personnel before final release of product.

3)Your firm did not implement controls to ensure the embecta manufacturing facility located in Holdrich Nebraska will follow the corporate level nonconformance procedure *CP60022 Control of Nonconforming Material/*Process, Revs 32 - 34, Eff. 04/26/2022 - 08/13/2025. Notably, your firm's manufacturing site will not open quality notifications per your firm's nonconformance procedure, section 6.1 -6.4 which states "All embecta locations must comply with the requirements of this document *** Any material, equipment, or processes that fail to meet specified inspection characteristics, workmanship standards or design specifications or was not manufactured in accordance with all appropriate procedures shall be handled as a Nonconformance using a Quality Notification (QN)***". On 5/15/2026, the quality lead for the manufacturing site explained that the firm will not open quality notifications for the rejected materials identified by the (b) (4) during routine production and that the overall rejects and scrap are trended together. Your firm's supplier tracks overall scrap throughout production but does not open quality notifications for instances of nonconforming product (scrap/rejects) found during routine production in many instances.

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OBSERVATION 4

Information gathered in the feedback process does not adequately serve as potential input into risk management for monitoring and maintaining product requirements as well as the product realization or improvement processes.

Specifically, your firm failed to adequately implement *CP60136 Risk Assessment Document Review Process,* Rev 4, Eff. 01/23/2026, in that your firm failed to adequately update risk documentation with post-market data. On 05/08/2026, your firm's management explained that they will not always update risk documentation with occurrence rates identified from complaints received. Notably,

1) Your firm provided *10000571556 Review of Risk Assessment for emebcta* (b) (4) *(FY25-FY26)*, Rev D, Eff. 04/17/2026, in which occurrence rates were higher than those within the risk assessment for identified harms "Damaged", "FM – Non-Biological", and "Open Package(b) (4)". The occurrence rates were not updated within the risk assessment file for your firm's (b) (4) products.

2) Your firm provided *10000597441 Review of Risk Assessment for embecta* (b) (4) *(FY24-FY25)*, Rev C, Eff. 07/15/2025, in which the occurrence rate for identified harm (b) (4)" was higher than the occurrence rate identified in your firm's risk assessment.

OBSERVATION 5

Procedures for timely complaint handling do not adequately include requirements and responsibilities for investigating complaints.

Specifically, your firm failed to adequately implement *CP62110 Complaint Investigation Procedure,* Revs 1 – 6, Eff. 04/25/2022 - 04/15/2026, *CP92021 US Adverse Event*, Revs 1-3, eff. 03/23/2023 – 11/02/2025, *CP92009 Adverse Event Reporting Policy*, Revs 1 – 6, Eff. 09/13/2022 – 01/16/2026, *CP62096 Complaints Management and Adverse Event Reporting*, Revs 1 – 10, Eff. 04/04/2022 – 09/09/2025, *CP62169 Product Complaints Reporting,* Revs, 1 – 11, Eff. 04/04/2022 – 04/15/2024, in

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that your firm did adequately open complaints per your procedures. Section 5.2.2 of your firm's *CP62096 Complaints Management and Adverse Event Reporting*, Revs 10, Eff. 09/09/2025, states "Based on the information received, ensures that complaint records are created for different Awareness dates; different Event dates; different Material and Lot numbers; different defects, hazards, and harms***". Your firm failed to open additional complaint records and conduct investigations for additional events/harms for complaints which indicated multiple harms, hazards, or defects. For example,

1. Complaint intake 006445, received on 10/15/2025, which led to complaint report 0009742, states in the event description "*** Product is being used "off label" *** they are complaining about "(b) (4) pain" ***". Your firm only opened one complaint for this intake, the complaint describes two different events/harms, off label use and (b) (4) pain, an additional complaint should have been opened to capture the two events/harms.
2. Complaint intake 004384, received on 03/24/2025, which led to complaint report 0006526, states in the event description "***They explained that it was used off-label for (b) (4) . Complaint of (b) (4) leaking from the (b) (4) ***". Complaint record 0006526 has reported issue "Leakage". No complaint record was opened to capture the off-label use of the medical device.
3. Complaint intake 005147, received on 05/29/2025, led to complaint record 0007663. The event description of the complaint record states "I am reaching out to express concern regarding the quality of a recent batch of (b) (4) we purchased, which we regularly use for (b) (4) in out medical practice *** Several of out patients have reported increased pain during their (b) (4) treatments *** Upon inspection, it appears that the (b) (4) may be (b) (4) ***". Complaint record 0007663 has reported issue "(b) (4) (Off Label Use)". Per your procedure, a complaint should have been opened which captures the (b) (4) pain, as well as the off-label use.

***DATES OF INSPECTION**

5/06/2026(Wed), 5/07/2026(Thu), 5/08/2026(Fri), 5/11/2026(Mon), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri), 5/27/2026(Wed), 5/28/2026(Thu), 6/02/2026(Tue), 6/03/2026(Wed)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

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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."