

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 12/8/2025-12/11/2025 FEI NUMBER 3003775292			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Michael P. Spears, Senior Vice President Regulatory Affairs & Quality Assurance					
FIRM NAME KCI POLYMEDICS BV		STREET ADDRESS Ambachtslaan 1031			
CITY, STATE, ZIP CODE, COUNTRY Peer, Limburg, 3990 Belgium		TYPE ESTABLISHMENT INSPECTED Manufacturer			
<p>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.</p> <p><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></p>					
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.</p> <p>Specifically, your firm's procedures <i>Validation Master Plan</i>, PRO 38.E.00 Rev 1 (dated 04/16/2009); <i>Validation Procedure</i>, SOP 38.E Rev 00 (dated 10/21/2010) to Rev 02 (dated 05/13/2013); and <i>Process Validation</i>, SAT-QP-09-05 Rev 13 (dated 05/29/2015) to Rev 36 (dated 09/04/2025) are inadequate. Between (b)(4) your firm has distributed a total of (b)(4) class II sterile <i>V.A.C. Whitefoam</i> devices (b)(4). Your firm failed to adequately validate the:</p> <p style="margin-left: 40px;">A. Cleaning process using the worst-case product. This includes but is not limited to the highest allowable levels of (b)(4). Your firm categorized washing as medium risk in your process risk files: <i>Manufacturing PFMECA - V.A.C. Whitefoam</i>, PFMECA-05-839542 Rev 5 (dated 06/11/2025) and <i>Risk Management Assessment</i>, RM-A-05-839518 Rev 4 (dated 10/30/2025). This applies to the:</p> <ol style="list-style-type: none"> 1) In-process wash: <i>Process Qualification (PQ) for WhiteFoam Production</i>, Protocol DOC-0000023933 Rev A (dated 10/05/2010) and Report DOC-0000023934 Rev A (dated 10/25/2010). 2) Final wash: <i>Final wash process Process Qualification Protocol for (b)(4) washing</i> 					
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<p style="text-align: center;"><i>machine #207 on WhiteFoam manufacturing process in KCI Polymedics, DOC-0000048199 Rev A (dated 10/07/2019) and Process Qualification Report for Final wash process with washing machine #207 on WhiteFoam manufacturing process on KCI Polymedics, DOC-0000048200 Rev A (dated 11/15/2019).</i></p> <p>B.Polymerization process using worst case production parameters. This includes but is not limited to temperature maximum/minimums and highest allowable levels of sulfuric acid and formaldehyde. At the time of inspection your firm was unable demonstrate the characteristics of the process parameters used in the process validations. Your firm categorized polymerization as a medium risk in your process risk files: <i>Manufacturing PFMECA - V.A.C. Whitefoam</i>, PFMECA-05-839542 Rev 5 (dated 06/11/2025) and <i>Risk Management Assessment</i>, RM-A-05-839518 Rev 4 (dated 10/30/2025). This applies to both Polymerization Oven #003 and #004 and is associated with:</p> <ul style="list-style-type: none"> 1) <i>Protocol, Small Polymerization Oven (Equipment 003) OQ</i>, DOC-0000021910 Rev A (dated 11/26/2009) and <i>Report, Small Polymerization Oven (Equipment 003) OQ</i>, DOC-0000021911 Rev A (dated 06/20/2010). 2) <i>Protocol, Large Polymerization Oven (Equipment 004) OQ</i>, DOC-0000021914 Rev B (dated 01/18/2010) and <i>Report, Large Polymerization Oven (Equipment 004) OQ</i>, DOC-0000021915 Rev A (dated 03/01/2010) <p>C.Acid pressing process. Specifically, the process is used to remove post-polymerization manufacturing residue/residuals (sulfuric acid, and formaldehyde,). Your firm did not challenge the process utilizing worst case process parameters.</p> <p>Between 01/01/2023 and 12/01/2025 your firm has received 53 complaints associated with the Class II sterile V.A.C. Whitefoam device. 9 of 53 allege foul odor, 3 of 53 allege injury, and 1 of 53 allege infection.</p>					
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OBSERVATION 2 <p>Procedures for monitoring and control of process parameters for a validated process have not been adequately established.</p> <p>Specifically, your firm failed to establish procedures to document start up temperatures and pressure settings for sealers #234, #235, and #236. The <i>PQ report</i> [REDACTED] sealers, SAT-PQ-RPT-05-899324 Rev 1 (dated 12/21/2022) defines in section 6.0 the nominal temperature as 140 °C and force/pressure as 100N. However, your firm's DHRs fail to document this parameter during start-up. For example:</p> <p style="margin-left: 40px;">In both batches [REDACTED] [REDACTED] devices, (dated [REDACTED]) and # [REDACTED]; [REDACTED] devices, (dated [REDACTED]) your firm fails to document the start-up parameters for both temperature and pressure</p>			
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Narakesh N Gomanie
Investigator
Signed By: NAAKESH N.
GOMANIE -S
Date Signed: 12-11-2025
15:23:25

DATE ISSUED

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."