**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314 | 4/15/2026-4/17/2026 |
| | FEI NUMBER<br>1000138377 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christian L. Quinto, Head of Quality and R&D

| FIRM NAME | STREET ADDRESS |
|---|---|
| MPM Medical LLC | 1801 Big Town Blvd Ste 300 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Mesquite, TX 75149-1030 | TYPE ESTABLISHMENT INSPECTED<br>Initial Importer |

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

One or more processes for risk management in product realization have not been adequately documented.

Specifically, the risk management processes for product preservation have not been adequately documented. Your Product Risk Analysis and Risk Management Procedure, Rev. 1, effective 07/09/2025, does not address risk management activities applicable to your firm's operations as an initial importer of finished medical devices, which include providing infrastructure and work environments specific to the products received. Additionally, your firm's nonconformance records and complaints include risks associated with potential product defects; however, the risk analysis has not been adequately documented.

## OBSERVATION 2

The inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements were not adequately established and implemented.

Specifically, your firm failed to adequately document the verification that purchased products conform to specified requirements. Your firm operates as an initial importer of Class I and Unclassified medical devices intended for use in wound care. According to your procedure, Receiving Inspection, Rev. 9,

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Katherine M Thames, Investigator<br>X Katherine M Thames Investigator Signed By: KATHERINE M. THAMES -S Date Signed: 04-17-2026 10:53:15 | 4/17/2026 |

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effective 10/07/2025, personnel must verify that outsourced finished goods conform to specified requirements. However, specific requirements for sterile medical devices are not adequately documented within your incoming inspection records.

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## Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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|---|---|---|---|
| **SEE REVERSE OF THIS PAGE** | EMPLOYEE(S) SIGNATURE<br>Katherine M Thames, Investigator | X Katherine M Thames Investigator Signed By: KATHERINE M. THAMES -S Date Signed: 04-17-2026 10:53:15 | DATE ISSUED<br>4/17/2026 |

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."