

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured and/or distributed according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2016 (BSI Certificate Number: FM 653694) in the USA.



 Alan E. Hatch  
 Sr. Quality Manager

 The following information represents Product Certification for: Item#: **177437**

 Certificate issued: **07/23/2021**

 Description: **CHAMBER SLIDE,4 WELL PERMNX**

 Lot#: **1323015**

 Use Before: **06/22/2026**

 Manufactured: **06/22/2021**

| Part Number | Description                     | Common Name                | DMF#  | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR |
|-------------|---------------------------------|----------------------------|-------|--------------|--------------|-------------------------|
| 0-581-98    | CHAMBER TC 4-CELL               | COMPONENT PART             |       |              |              |                         |
| 14149MR     | RESIN,POLYSTYRENE               | NATURAL, POLYSTYRENE, INJ. | 18492 | PASSED       | PASSED       | 177.1640                |
| 0-583-98    | CHAMBER TC COVER                | COMPONENT PART             |       |              |              |                         |
| 14149MR     | RESIN,POLYSTYRENE               | NATURAL, POLYSTYRENE, INJ. | 18492 | PASSED       | PASSED       | 177.1640                |
| 0003898     | SLIDE PERMANOX                  | COMPONENT PART             |       |              |              |                         |
| 7002MR      | RESIN,TPX,RT18XB                | TPX,RT18XB                 | N/A   | N/A          | N/A          | N/A                     |
| 120225LE    | Silicone,Dow ,MDX4-4210,Permnox | SILICONE ADHESIVE          | 2811  | PASSED       | PASSED       | 177.2600                |

If N/A appears in any of the columns above it means the information is not available. Any item listed as "COMPONENT PART" will show blank in the DMF#, Cytotoxicity, USP Class VI, and FDA Compliance Information columns.

If the word "PASSED" appears in the USP Class VI column next to the resin listing, this material has passed USP Class VI requirements, latest Volume, as part of our initial test approval protocol.

If the word "PASSED" appears in the Cytotoxicity column next to the resin listing, this material was tested and shown to be non-cytotoxic as part of our initial test approval protocol, using either mouse fibroblast L929 cells or the more sensitive human diploid lung cell lines WI-38 or MRC-5.

Product has been ETO Sterilized. Product was released per ANSI/AAMI/ISO 11135 guidelines. Product was determined to be non-pyrogenic at a level < 0.5 EU/ml per USP < 85 > .

This product is in compliance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. CE