*EUROPEAN MEDICAL DEVICE REGULATION*

# Declaration of Conformity

As Legal Manufacturer, we

3M Deutschland GmbH
Health Care Business
Single Registration Number DE-MF-000011641
Carl-Schurz-Str. 1
41453 Neuss
Germany

hereby declare under our sole responsibility that the following CE marked devices

| | |
|---|---|
| Trade Name | **Tegaderm™ Transparent -** IV Transparent Film Dressing with Border<br>**Tegaderm™ Film -** Transparent Film Dressing Frame Style<br>**Tegaderm™ Film -** Transparent Film Dressing with Border |
| Intended Purpose | Dressing can be used to cover and protect catheter sites and wounds, to maintain a moist environment for wound healing or to facilitate autolytic debridement, as a secondary dressing, as a protective cover over at-risk skin, to secure devices to the skin, to cover first and second degree burns and as a protective eye covering. |
| Reference (Products made in Germany) | **1633, 1635, 1655, 1623W, 1624W, 1626W** |
| Basic UDI-DI (Products made in Germany) | 06082232761010000000000CB |
| Reference (Products made in USA) | **1610, 1655, 1622W, 1624W, 1626, 1626W, 1627, 1628, 1629, 1630 1614, 1616** |
| Basic UDI-DI (Products made in USA) | 06082232761010000000051CU |

are classified per rule 4 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class 2a sterile devices in accordance with Annex IX and all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

This declaration is made based on the quality assurance certificate
EC Certificate Number: 003626 MDR2017Q
Issued by: DQS Medizinprodukte GmbH, No. 0297

November 28, 2023

Harald Ceschinski
Senior Manager Regulatory Affairs and Quality
Health Care Business EMEA
3M Deutschland GmbH

Date