

**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 Tegaderm™ Film - Transparent Film Dressing Frame Style 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)	0608223276101000000000CB
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

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

November 28, 2023

Date

3M is a trademark of 3M.

Related to REG-STED-MDR-05-522836