

**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™ HP Transparent Film Dressing Frame Style Tegaderm™ HP I.V. Securement Dressing
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)	9536HP, 9546HP
Basic UDI-DI (Products made in Germany)	06082232761010000000052CW
Reference (Products made in USA)	9534HP, 9536HP, 9546HP 9519HP, 9525HP, 9634HP
Basic UDI-DI (Products made in USA)	06082238401010000000184AX

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

Claudia Inden
Manager Regulatory Affairs
3M Deutschland GmbH

September 6, 2024

Date