



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 device(s)

Trade Name	Tegaderm™ + Pad
Intended Purpose	Film dressing with non-adherent pad
Reference	3582E, 3584E, 3586E, 3589E, 3590E, 3591E, 3593E, 3582NP, 3584NP, 3586NP, 3589NP, 3582SP, 3586SP, 3590SP, 3582P, 3586P, 3589P, 3590P, 3582P-10, 3586P-10, 3582IP, 3586IP, 3589IP, 3582PR, 3586PR
Basic UDI-DI	06082232761010000000048D7

are classified per rule 4 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIa 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
EU Quality Management Certificate: 003626MDR2017Q
Issued by: DQS Medizinprodukte GmbH, No. 0297

Claudia Inden
Manager Regulatory Affairs
3M Deutschland GmbH

November 28, 2024
Date

3M is a trademark of 3M.

Related to REG-STED-MDR-05-855003