# *EUROPEAN MEDICAL DEVICE REGULATION*

## Declaration of Conformity

*As Legal Manufacturer, we*

3M Company
Single Registration Number: US-MF-000014086
2510 Conway Ave. St. Paul, MN 55144 USA

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

| | |
|---|---|
| Trade Name | 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing |
| Intended Purpose | Used to cover and protect catheter sites and to secure devices to skin; intended to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters. |
| Reference | 1657R, 1658R, 1659R, 1660R, 1877R, 1879R |
| Basic UDI-DI | 06082238401010000000129Z |

are classified per rules 4 and 14 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class III 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 Management System Certificate and Technical Documentation Assessment Certificate.

EU Quality Management System Certificate Number: MDR 725200
EU Technical Documentation Assessment Certificate: MDR 725050
Issued by: BSI, 2797

EU Authorized Representative:

3M Deutschland GmbH
Health Care Business
Single Registration Number: DE-AR-000011642
Carl-Schurz-Str. 1
41453 Neuss, German

DocuSigned by:
Mary Fretland
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St.Paul, MN 8/2/2024

Mary Fretland
Senior Regulatory Affairs Manager
Medical Surgical (MedSurg) Business

Location/Date

**3M and Tegaderm are trademarks of 3M.**