

## 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 <sup>™</sup> Tegaderm <sup>™</sup> CHG Chlorhexidine Gluconate I.V. Securement Dressing |
|--------------|--|
| Intended     | Used to cover and protect catheter sites and to secure devices to skin; intended           |
| Purpose      | 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:

2/27/2023

Nadia Battah, Regulatory Affairs Manager 3M Company 2510 Conway Ave. St. Paul, MN 55144 USA Date

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