# *EUROPEAN MEDICAL DEVICE REGULATION*

## Declaration of Conformity

As Legal Manufacturer, we

3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss
Germany

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

| | |
|---|---|
| Trade Name | 3M Tegaderm™ Roll |
| Intended Purpose | 3M Tegaderm™ Roll Transparent Film Dressing is intended for use as a secondary dressing (e.g. used over and in combination with a primary sterile dressing); as a protective cover over at risk, intact skin; to secure devices to the skin; and as a waterproof fixation cover (e.g. to protect devices and primary dressings from outside fluid or water). |
| Reference | 16002, 16004, 16006, 16004S |
| Basic UDI-DI | 06082327610100000000016CS |

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

Margaret Bessenbach

Margaret Bessenbach
Manager Regulatory Affairs and Quality
Health Care Business EMEA
3M Deutschland GmbH

February 6, 2020
Date