# *EUROPEAN MEDICAL DEVICE REGULATION*

## Declaration of Conformity

*As Legal Manufacturer, we*

3M Company
Single Registration Number (TBD)
2510 Conway Ave. St. Paul, MN 55144 USA

*hereby declare under our sole responsibility that the following CE marked device(s)*

| | |
|---|---|
| Trade Name | Cavilon™ No Sting Barrier Film |
| Intended Purpose | Polymeric solution that forms a long-lasting uniform film for protection of intact or damaged skin from irritation, friction, and shear. |
| Reference | 3346E, 3346P: 28ml bottle<br>3346N, 3346NP: 28ml bottle (for Nordic market) |
| Basic UDI-DI | 06082238401010000000018AD |

are classified per rules 1 and 4 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.

The Authorized European Representative for the concerned devices is

3M Deutschland GmbH
Health Care Business
Single Registration Number (TBD)
Carl-Schurz-Str. 1
41453 Neuss, Germany

Dianne Gibbs

Dianne Gibbs, Division Regulatory Affairs Manager
3M Company
2510 Conway Ave. St. Paul, MN 55144 USA

13 May 2020
Date