

## 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 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
	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: DE-AR-000011642 Carl-Schurz-Str. 1 41453 Neuss, Germany

Dianne Gibbs, RAC

Regulatory Affairs Director 3M Medical Solutions Division Location/Date

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