

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	3M TM Cavilon TM 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	1ml wand: 3343E, 3343P 1ml wipe: 3344E 3ml wand: 3345E, 3345P	For the Nordic market: 1ml wand: 3343N 3ml wand: 3345N
Basic UDI-DI	0608223840101000000092AR	

are classified per rule 4 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class Is 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 assurance certificate EC Certificate Number: MDR 725202 Issued by: BSI, 2797

The Authorized European Representative for the concerned device(s) is

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

DocuSigned by: adia Battah

3/7/2023

Date

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

3M is a trademark of 3M.