

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	Nexcare™ Waterproof Bandages Nexcare™ Aqua Clear Waterproof Bandages Nexcare™ Aqua Clear MAXI Waterproof Bandages Spofaplast™ Tattoo™ Waterproof Spofaplast™ Tattoo™ Waterproof Plasters Viscoplast™ Waterproof Tattoo™ Viscoplast™ Waterproof Tattoo™ Plasters Viscoplast™ Aqua Clear Waterproof Plasters Nexcare Aqua WP Plasters Sample Pack Tattoo™
Intended Purpose	Bandages are used to cover and protect minor wounds
Reference	582-10DN 586-20DN 588-30DN N0610NAKDMN N1205DMN N126ASDX02N N1214ASD01N N16-12-1MOP 12100HD1N 12100HD2N 115N 115P V5D28K10N V12-14-3 V16-12-1P 02N
Basic UDI-DI	06082238401050000000009E8

are classified per rule 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 device(s) is

EU Representative Address
3M Deutschland GmbH
Health Care Business
DE-AR-000011642
Carl-Schurz-Str. 1
41453 Neuss, Germany

DocuSigned by:

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4/4/2024

Joe Coskey
Regulatory Manager
Consumer Health Care
Consumer Business Group
3M Company

Date

3M, Nexcare, Spofaplast, and Viscoplast are trademarks of 3M.