3M Health Care Business

3M Center
2510 Conway Ave, Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Company, 3M Health Care,
3M Center, 2510 Conway Ave, Bldg. 275-5W-06
Saint Paul, MN 55144 USA
hereby declare under our sole responsibility
that the CE marked products to which this declaration relates ,

3M™ Tegaderm™ + Pad Film Dressing with Nonadherent Pad
Product numbers:
3582, 3582NP, 3582P, 3582IP, 3582P-10, 3582SP, 3584, 3584NP, 3584P, 3584IP, 3586, 3586NP, 3586P, 3586SP, 3586IP, 3586P-10, 3587, 3588, 3589, 3589NP, 3589P, 3589SP, 3589IP, 3590, 3590P, 3590SP, 3590IP, 3591, 3591IP, 3591P, 3593

Viscoplast™ Tegaderm™ + Pad Waterproof Dressing
Product numbers:
3582VE, 3584VE, 3586VE, 3589VE

Viscoplast Waterproof Dressing with Absorbent Pad Tegaderm™ + Pad
Product Numbers:
3582V, 3584V, 3586V, 3589V

Nexcare™ Tegaderm™ + Pad Waterproof Dressing
Product numbers:
TP0610, TP0915

are classified,
per Rule 4 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as a Class IIa device
and

are in accordance with Annex V and Annex VII of Directive 93/42/EEC, as amended per 2007/47/EC on the approximation of the laws of the Member States concerning medical devices.

In addition, we declare that the above mentioned devices fulfil the applicable provisions of the Directive 93/42/EEC, as amended per 2007/47/EC.

This declaration is made on the basis of the quality assurance certificate CE00493 delivered by BSI, 2797

EU Representative Address
3M Deutschland GmbH
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41453 Neuss, Germany

Signature: _____ Date: 1 November 2019

Dianne L. Gibbs
3M Health Care
Division Regulatory Affairs Manager
Medical Solutions Division

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