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
St. Paul, MN 55144 USA
hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

3M™ Tegaderm™ I.V. Transparent Film Dressing with Border
1610, 1650, 1655

3M™ Tegaderm™ Film Transparent Film Dressing with Border
1614, 1616

3M™ Tegaderm™ Film Transparent Film Dressing Frame Style
1622NP, 1622P, 1622IP, 1622SP, 1622W, 1622W/5, 1624NP, 1624P, 1624IP, 1624SP, 1624W, 1624W/5, 1624W/10, 1624P-10, 1626, 1626NP, 1626P, 1626IP, 1626SP, 1626W, 1626W/5, 1626W/10, 1626P-10, 1627, 1628, 1629, 1630, 1630NP, 1630P, 1630IP, 1630SP, 1630W/5, 1632P-10, 1634, 9505W, 9506W

3M™ Nexcare™ Tegaderm™ Transparent Dressing
T1012

is 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

is 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 European Union 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 CE 00493 delivered by BSI, 2797

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

Signature: Karen Leigh FOR DIANNE GIBBS Date: 10 MAY 2019

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

REG-DOC-05-129792, Tegaderm Transparent Film Dressings, Version 7,
Status: Release, Release Date: 05/09/2019 07:49:10 AM CDT

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