3M Health Care Business

2510 Conway Ave
St Paul, MN 55144
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Health Care Business,
2510 Conway Ave
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, 1622W, 1622W/5, 1624W, 1624WB KUT, 1624WBLK, 1626, 1626NP, 1626W, 1626W/5, 1626W/10, 1626WB KUT, 1626WBLK, 1627, 1628, 1629, 1630, 1630NP, 1630W/5, 1634, 9505W, 9506W

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

are in accordance with Annex V 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, 0086

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

Signature: _____ Date: 31 Jan 2013

Maria J. Westfall
3M Health Care
Vice President, Regulatory Affairs and Quality Assurance
Skin & Wound Care Division

REG-DOC-05-129792, Tegaderm Transparent Film Dressings, Version 2,
Status: Release, Release Date: 1/31/2013 1:27:18 PM

THIS DOCUMENT WAS PRINTED ON 31-Jan-2013 1:39 PM