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 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<sup>TM</sup> Tegaderm<sup>TM</sup> I.V. Transparent Film Dressing with Border 1610, 1650, 1655

3M<sup>™</sup> Tegaderm<sup>™</sup> Film Transparent Film Dressing with Border 1614, 1616

3M<sup>TM</sup> Tegaderm<sup>TM</sup> Film Transparent Film Dressing Frame Style 1622NP, 1622W, 1622W/5, 1624NP, 1624W, 1624W/5, 1624W/10, 1626, 1626NP, 1626W, 1626W/5, 1626W/10, 1627, 1628, 1629, 1630, 1630NP, 1630W/5, 1634, 9505W, 9506W

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, 0086

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

Date: 24 FEB 2015

Signature: 1

Karen Rittle
3M Health Care

Division Regulatory Affairs Manager Critical & Chronic Care Solutions Division

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