**3M Health Care Business** 

3M Center St. Paul, MN 55144-1000 651 733 1110



## Declaration of Conformity

We, 3M Health Care, hereby declare under our sole responsibility that the CE marked products to which this declaration relates,

3M<sup>™</sup> Tegaderm<sup>™</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>™</sup> Tegaderm<sup>™</sup> 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

This certificate is valid for devices originating from the following sites: 3M Brookings Manufacturing Facility 601 22nd Ave. South Brookings, South Dakota 57006 U.S.A. EU Representative Address 3M Medica

3M Medica Zweigniederlassing der 3M Deutschland GmbH Trading as "3M Health Care" Hammfeldamm 11 D-41453 Neuss, Germany

Signature:

Date: 02/23/2010

Kathryn W. Foran 3M Health Care Regulatory Affairs and Quality Assurance Skin & Wound Care Division

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