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, 2510 Conway Ave St. Paul, MN 55144 U.S.A.

hereby declare under our sole responsibility that the CE marked products to which this declaration relates ,

 $3M^{\text{TM}}$ Ioban $^{\text{TM}}$ 2 Antimicrobial Incise Drapes: 6640EZ, 6650EZ, 6651EZ, 6640EZSB, 6648EZSB, 6650EZSB, 6651EZSB, 6640EZE, 6650EZE, 6650EZE, 6650EZBE, 6650EZBE, 6651EZBE

3M[™] Ioban[™] 2 Antimicrobial Incise Drapes (Frame Delivery) 6661EZ, 6661EZSB

are classified, per rule 13 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC, as Class III devices and

are in accordance with Annex II 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 EC Design Dossier Certificate 89073 and the full quality assurance certificate EC 02242 delivered by BSI, 2797

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

Signature:

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3M Health Care

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Medical Solutions Division

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