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 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 Electrosurgical Pads
Product Numbers
1146, 1148-LP, 1149, 1149C-LP, 1149F, 1179, 1180, 1180F, 1181, 1182, 8149F, 8180F, 9130, 9130F, 9135-LP, 9160, 9160F, 9165, 9165L

is classified,
per Rule 9 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as a Class IIb device
and

is 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 fulfill 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 02242 delivered by BSI, 0086

3M Health Care Business self-declares conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and compliance to the requirements of EN 50581:2012.

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

Signature: _____ Date: 21 December 2016

Dianne Gibbs
Regulatory Affairs Manager
Infection Prevention Division
3M Heath Care

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