3M Health Care Business

3M Center
2510 Conway Ave, Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
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Declaration of Conformity

As Legal Manufacturer
We, 3M Company, 3M Health Care,
3M Center, 2510 Conway Ave, Bldg. 275-5W-06
Saint Paul, MN 55144 USA
hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

3M Monitoring Electrodes
Product numbers:
2228, 2228-3, 2228-5, 2228BA, 2244

are classified,

per Rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC

as a Class I device, and

are in accordance with Annex VII of Directive 93/42/EEC, as amended per 2007/47/EC, on the approximation of the laws of the European Member States concerning medical devices.

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
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Signature: Dianne L. Gibbs Date: 16 September 2015

Dianne L. Gibbs
3M Health Care
Division Regulatory Affairs Manager
Infection Prevention Division

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