3M Company

2510 Conway Ave,
St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Company,
2510 Conway Ave,
Saint Paul, MN 55144 USA
hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,
3M Red Dot™ Monitoring Electrode with Foam Tape
Product Numbers:
2228, 2228-3 and 2228-5

3M Red Dot™ Monitoring Electrode with 4 mm Adapter
Product Numbers:
2228BA

3M Red Dot™ Radiolucent Monitoring Electrode with Foam Tape
Product Number:
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 Company 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: 29 January 2020

Dianne L. Gibbs
3M Company
Division Regulatory Affairs Manager
Medical Solutions Division

REG-DOC-05-133303, 3M Red Dot™ Monitoring Electrode with Foam Tape; 3M Red Dot™ Monitoring Electrode with 4 mm Adapter; 3M Red Dot™ Radiolucent Monitoring Electrode with Foam Tape, Version 7,
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