EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company
Single Registration Number (TBD)
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the following CE marked device(s)

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

Trade Name*	3M Red Dot™ Monitoring Electrode with Foam Tape and Sticky Gel 3M Red Dot™ Radiolucent Monitoring Electrode with Foam Tape, Sticky Gel and Abrader Pad 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
Intended Purpose	The 3M™ Red Dot™ Monitoring Electrode with Foam Tape and Sticky Gel 2560 is intended to be used by healthcare professionals for ECG monitoring. This electrode is disposable, intended for single use, and has been tested for up to 5 days wear. The 3M™ Red Dot™ Monitoring Electrode with Foam Tape and Sticky Gel 2570 series are intended to be used by healthcare professionals for ECG monitoring. These electrodes are disposable, intended for single use, and have been tested for up to 5 days wear. The 3M™ Red Dot™ Foam Monitoring Electrode 2228 and the 3M™ Red Dot™ Foam Monitoring Electrode with 4mm Adapter 2228BA are intended to be used by healthcare professionals for ECG monitoring. These electrodes are disposable, intended for single use, and have been tested for up to 3 days wear. The 3M™ Red Dot™ Radiolucent Monitoring Electrode with Foam Tape 2244 is intended to be used by healthcare professionals for ECG monitoring. This electrode is disposable, intended for single use, and has been tested for up to 3 days wear
Reference	2560, 2560-3 & 2560-5 2570, 2570-3 & 2570-5 2228 & 2228BA 2244
Basic UDI-DI	06082238401010000000042AA

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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.

The Authorized European Representative for the concerned device(s) is:

3M Deutschland GmbH
Health Care Business
Single Registration Number (TBD)
Carl-Schurz-Str. 1
41453 Neuss, Germany

Dianne Gibbs, Division Regulatory Affairs Manager
3M Company
2510 Conway Ave. St. Paul, MN 55144 USA

3 September 2020
Date

*3M and Red Dot are trademarks of 3M.

Issued to Authorized Representative

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