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)

Trade Name*	3M Red Dot™ Diaphoretic Monitoring Electrode with Soft Cloth Tape and Solid Gel 3M Red Dot™ Monitoring Electrode with Soft Cloth Tape and Solid Gel 3M Red Dot™ Monitoring Electrode, with Micropore™ Tape and Solid Gel 3M Red Dot™ Monitoring Electrode Small Size, with Soft Cloth Tape
Intended Purpose	The 3M™ Red Dot™ Monitoring Electrode 2200 series* are intended to be used by healthcare professionals for ECG monitoring. The 2245-50 and 2248-50 electrodes can be used for ECG monitoring of pediatrics
Reference	2231 & 2271-50 2238 & 2255 2239, 2248-50 & 2249-50 2245-50
Basic UDI-DI	06082238401010000000041A8

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.

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

21 August 2020

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

Date

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

Issued to Authorized Representative

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