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 devices

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	Electrocardiograph (ECG) electrode
Reference	2231 & 2271-50 2238 & 2255-50 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, as amended per (EU) 2015/863, and compliance to the requirements of EN IEC 63000:2018.

EU Authorized Representative:

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

Dianne Gibbs
Regulatory Affairs Director
3M Company

11 August 2021
Date

3M and Red Dot are trademarks of 3M.