

**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

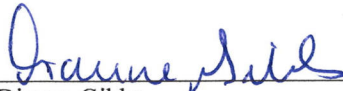
Trade Name	3M™ Red Dot™ Diaphoretic Monitoring Electrode with Soft Cloth Tape and Solid Gel 3M™ Red Dot™ Monitoring Electrode with Soft Cloth Tape and Solid Gel 3M™ Red Dot™ Monitoring Electrode, with Micropore™ Tape and Solid Gel 3M™ Red Dot™ Monitoring Electrode Small Size, with Soft Cloth Tape
Intended Purpose	Electrocardiograph (ECG) electrode
Reference	2231 & 2271-50 2238 & 2255-50 2239, 2248-50 & 2249-50 2245-50
Basic UDI-DI	06082238401010000000041A8

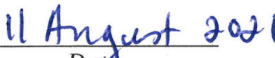
are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

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)  
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41453 Neuss, Germany

  
Dianne Gibbs  
Regulatory Affairs Director  
3M Company

  
Date

3M and Red Dot are trademarks of 3M.