

**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)*

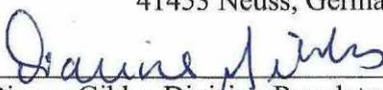
|                  |   |
|------------------|---|
| Trade Name*      | 3M Red Dot™ Diaphoretic Monitoring Electrode with Soft Cloth Tape and Solid Gel<br>3M Red Dot™ Monitoring Electrode with Soft Cloth Tape and Solid Gel<br>3M Red Dot™ Monitoring Electrode, with Micropore™ Tape and Solid Gel<br>3M Red 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<br>2238 & 2255<br>2239, 2248-50 & 2249-50<br>2245-50   |
| Basic UDI-DI     | 06082238401010000000041A8   |

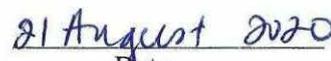
are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

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, 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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