



EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company

Single Registration Number: US-MF-000014086

2510 Conway Ave. St. Paul, MN 55144 USA

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

Trade Name	<ol style="list-style-type: none"> 1. Red Dot™ Monitoring Electrode with Foam Tape and Sticky Gel 2. Red Dot™ Radiolucent Monitoring Electrode with Foam Tape, Sticky Gel and Abrader Pad 3. Red Dot™ Monitoring Electrode with Foam Tape 4. Red Dot™ Monitoring Electrode with 4 mm Adapter 5. Red Dot™ Radiolucent Monitoring Electrode with Foam Tape
Intended Purpose	<ol style="list-style-type: none"> 1. Monitoring Electrode with Foam Tape and Sticky Gel 2. Radiolucent Monitoring Electrode with Foam Tape, Sticky Gel and Abrader Pad 3. Monitoring Electrode with Foam Tape 4. Monitoring Electrode with 4 mm Adapter 5. Radiolucent Monitoring Electrode with Foam Tape
Reference	<ol style="list-style-type: none"> 1. 2560, 2560-3 & 2560-5 2. 2570, 2570-3 & 2570-5 3. 2228 4. 2228BA 5. 2244
Basic UDI-DI	0608223840101000000042AA

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 IEC 63000:2018.



EU Authorized Representative:

EU Representative Address
3M Deutschland GmbH
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Carl-Schurz-Str. 1
41453 Neuss, Germany

Signed by:


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Mary Fretland
Senior Regulatory Affairs Manager
Medical Surgical (MedSurg)

St. Paul, MN 9/11/2025

Location/Date

3M is a trademark of 3M.