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 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
Intended Purpose	Electrocardiograph (ECG) electrode
Reference	2231 2238 2239, 2248-50 & 2249-50
Basic UDI-DI	06082238401010000000041A8

are classified per rule I 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 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
Health Care Business
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Carl-Schurz-Str. 1
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DocuSigned by:
Mary Fretland
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St.Paul, Minnesota 7/19/2024

Mary Fretland
Senior Regulatory Affairs Manager
Medical Surgical (MedSurg)

Location/Date