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

Trade Name*	3M Red Dot™ Resting EKG Electrode
Intended Purpose	The 3M™ Red Dot™ Resting EKG Electrodes 2330 and 2360 are intended to be used by healthcare professionals on adults undergoing a short-term diagnostic EKG procedure while resting. The 2330 electrode can also be used on adults with fragile skin and pediatrics.
Reference	2330 2330* 2360
Basic UDI-DI	06082238401010000000046AJ

**The packaging configuration of this electrode includes a secondary level of packaging*

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 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

18 September 2020
Date

*3M and Red Dot are trademarks of 3M.

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