



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™ Defib-Pads
Intended Purpose	External cardioversion defibrillator electrode pads
Reference	2345N, 2346N
Basic UDI-DI	06082238401010000000072AK

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: DE-AR-000011642

Carl-Schurz-Str. 1

41453 Neuss, Germany

DocuSigned by:


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Nadia Battah

Regulatory Affairs Manager

3M Company

3M Medical Solutions Division

5/11/2023

Date

3M is a trademark of 3M.