



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	Steri-Strip™ Steri-Strip™ Reinforced Skin Closures
Intended Purpose	Steri-Strip Skin Closures are intended for use as skin closure devices in the treatment of lacerations and surgical incisions. They may be used in conjunction with skin sutures and staples or after their removal for wound support.
Reference	1540P-1, 1540P-2, 1540P-12, 1541P-1, 1541P-2, 1541P-12, 1542P-1, 1542P-2, 1547P-1, 1547P-12, 1540IP-1, 1540IP-2, 1540IP-12, 1541IP-1, 1541IP-12, 1542IP-1, 1546IP-1, 1546IP-12, 1547IP-1, 1547IP-12, 1540NP-2, 1540NP-12, 1541NP-2, 1541NP-12, 1542NP-12, 1546NP-1, 1546NP-12, 1547NP-1, 1547NP-12, 1541SP-2, R1540-02, R1541-02, 1546P-1
Basic UDI-DI	06082238401010000000068AU

is classified per rule 4 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class Is devices in accordance with Annex IX and all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

This declaration is made based on the quality assurance certificate
EC Certificate Number: MDR 725202
Issued by: BSI, 2797

The Authorized European Representative for the concerned device(s) is

EU Representative Address
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 Medical Solutions Division

8/23/2023

Date

3M and Steri-Strip are a trademark of 3M.

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Issued to Authorized Representative (EC REP)