3M Health Care Business

3M Center 2510 Conway Ave, Bldg. 275-5W-06 St. Paul, MN 55144 U.S.A. 651 733 1110



Declaration of Conformity

As Legal Manufacturer We, 3M Company, 3M Health Care, 3M Center, 2510 Conway Ave, Bldg. 275-5W-06 Saint Paul, MN 55144 USA hereby declare under our sole responsibility that the CE marked products to which this declaration relates,

3M[™] Steri-Strip[™] Skin Closures (Reinforced)

R1540, R1540-01, R1540-02, R1540-12, R1541, R1541-01, R1541-02, R1541-12, R1542, R1542-01, R1542-12, R1546, R1546-01, R1546-12, R1547, R1547, 01, R1547-12, R1548, R1549, 1540P-1, 1540P-2, 1540P-12, 1541P-1, 1541P-2, 1541P-12, 1542P-1, 1542P-2, 1546P-1, 1547P-1, 1547P-12, 1540IP-1, 1540IP-2, 1540IIP-2, 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-12, 1546NP-12, 1547NP-12, 1541SP-2 3MTM Steri-StripTM Blend Tone Skin Closures

B1551, B1557, B1559, B1551-02, B1551-12, 1551NP-2, 1551NP-12, 1551SP-2

3M[™] Steri-Strip[™] Elastic Skin Closures

E4541, E4541-12, E4542, E4547, E4548, E4549, 4541-12, 4541NP-12

3M[™] Steri-Strip[™] Wound Closure System

W8512, W8514, W8516

3M[™] Steri-Strip[™] Skin Closure Rack, 1555

3M[™] Steri-Strip[™] Compound Benzoin Tincture, C1544

Nexcare(tm) Steri-Strip[™] First Aid Skin Closures

R150C

M-Plast Wundverschluss-Streifen 5203.531

3M[™] Nexcare[™] Steri-Strip[™] First Aid Skin Closures

SS08

Viscoplast[™] Steri-Strip[™] First Aid Skin Closures 1540RV, 1541RV, 1542RV, R150V, R1551V

Spofaplast® Steri-Strip[™] First Aid Skin Closures

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are classified, per Rule 4 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC as a Class Is device

and

is in accordance with Annex(es) V (sterilization) and VII of Directive 93/42/EEC, as amended per 2007/47/EC, on the approximation of the laws of the European Union Member States concerning medical devices.

This declaration is made on the basis of the quality assurance certificate CE 00493 delivered by BSI, 2797

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

Signature:

Dianne Gibbs 3M Health Care Regulatory Affairs Director Medical Solutions Division

6 May 2021 Date:

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