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, 15401IP-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-1, 1546NP-12, 1547NP-1, 1547NP-12
1541SP-2

3M™ Steri-Strip™ Blend Tone Skin Closures
B1550, B1551, B1553, B1557, B1559, B1551-02, B1551-12, 1551NP-2, 1551NP-12, 1551SP-2

M™ Steri-Strip™ Elastic Skin Closures
E4540, E4541, E4541-12, E4542, E4546, 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

3M™ Steri-Strip™ Skin Closures for Consumer
R150C (Nexcare), 5203.531 (M-Plast)

3M™ Nexcare™ Steri-Strip™ First Aid Skin Closures
SS08

Viscoplast Steri-Strip™ Closures
1540R, 1541R, 1542R, R150C, R1551V

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, 0086

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

Signature: Karen Rittle Date: 12 MAY 2017

Karen Rittle
3M, 3M Health Care
Division Regulatory Manager
Critical & Chronic Care Solutions Division

REG-DOC-05-000036, Steri-Strip Wound Closures, Version 11,
Status: Release, Release Date: 05/11/2017 03:26:30 PM CDT

THIS DOCUMENT WAS PRINTED ON 12-May-2017 10:41 AM

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 00493**

Issued To:

3M Company
3M Health Care
dba 3M Consumer Health Care
2510 Conway Ave.
Saint Paul
Minnesota
55144
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1995-02-01** Date: **2020-03-15** Expiry Date: **2024-05-26**

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By Royal Charter

Certificate No: CE 00493

Certificate Scope:

The manufacture of sterile transparent wound dressings with and without pads, electronic stethoscopes and associated software, sterile skin staplers and sterile drapes (wound protector, isolation bag), barrier film dressings, and sterile disinfecting port protector devices.

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of wound closures, wound dressings, drapes, barrier film wraps, staple removers, patient warming blankets and securement devices.

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Device Directive.

First Issued: **1995-02-01** Date: **2020-03-15** Expiry Date: **2024-05-26**