

EC Certificate - Production Quality Assurance

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00493**
Date: **2020-03-15**
Issued To: **3M Company**
3M Health Care
dba 3M Consumer Health Care
2510 Conway Ave.
Saint Paul
Minnesota
55144
USA

| Subcontractor: | Service(s) supplied |
|--|--|
| 3M Company 905 Adams St. SE Hutchinson Minnesota 55350 USA | Manufacture |
| 3M Deutschland GmbH Healthcare Business Carl-Schurz - Str. 1 41453 Neuss Germany | Control of Sterilization EU Representative Secondary Packaging |
| 3M Deutschland GmbH Health Care Business Plant Kamen Edisonstraße 6 59174 Kamen Germany | Manufacture |

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Subcontractor:

Service(s) supplied

3M Company
10351 West 70th Street
Eden Prairie
Minnesota 55344
USA

Manufacture

3M Company
5400 Paris Road
Columbia
Missouri
65202
USA

Manufacture

3M Company
601 22nd Ave. South
Brookings
South Dakota 57006
USA

**Gamma Sterilization
Manufacture**

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Supplementary Information to CE 00493

Issued To:

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| NBOG code(s) | Device description |
|-----------------|--|
| Class Is | |
| MDS 7006 | 3M™ Cavilon™ No Sting Barrier Film (Wipes/wands) |
| MDS 7006 | 3M™ Bair Hugger™ Warming Blankets (Sterile) |
| MDS 7006 | 3M™ Coban™ Self-Adherent Wrap (Sterile) |
| MDS 7006 | 3M™ Steri-Strip™ Closures |
| MDS 7006 | 3M™ Medipore™ +Pad Cloth Adhesive Wound Dressing |
| MDS 7006 | 3M™ Steri-Drape™ Surgical Drape and Accessories |
| MDS 7006 | 3M™ Skin Stapler Remover |
| MDS 7006 | 3M™ Nexcare™ Bandages |

First Issued: **1995-02-01**

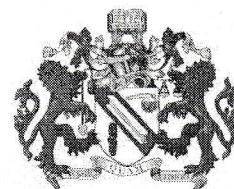
Date: **2020-03-15**

Expiry Date: **2024-05-26**

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Page 4 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.



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| NBOG code(s) | Device description |
|------------------|---|
| Class IIa | |
| MD 0301 | 3M™ Tegaderm™ Transparent Film Dressing |
| MD 0301 | 3M™ Tegaderm™ I.V. Advanced Securement Dressing and 3M™ Tegaderm™ Diamond Pattern Film Dressing |
| MD 0301 | 3M™ Tegaderm™ HP Transparent Film Dressing Frame Style |
| MD 0301 | 3M™ Tegaderm™ Transparent Film Dressing First-Aid Style |
| MD 0301 | 3M™ Tegaderm™ I.V. Transparent Film Dressing with Adhesive-Free Window |
| MD 1301 | 3M™ Littmann® Electronic Stethoscope and software |
| MD 0302 | 3M™ Precise™ Disposable Skin Stapler with Staples |
| MD 0303 | 3M™ Steri-Drape™ Isolation Bag and Wound Edge Protector Drape |
| MD 0303 | 3M™ Cavilon™ Advanced Skin Protectant |
| MD 0301 | 3M™ Tegaderm™ + Pad Film Dressing with Nonadherent Pad |
| MD 0108 | 3M™ Curoc™ Disinfecting Caps, Tips, and Cap Strips |

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Page 3 of 4

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

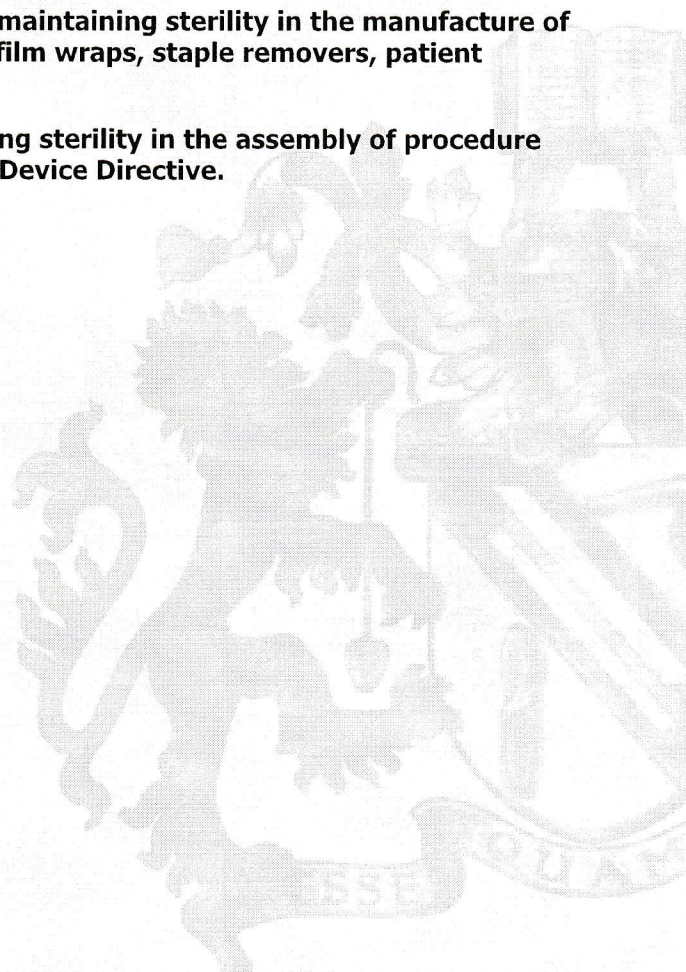
Certificate No: CE 00493

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.



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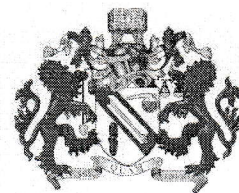
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Page 2 of 4

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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

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Page 1 of 4

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