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# 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<br>905 Adams St. SE<br>Hutchinson<br>Minnesota 55350<br>USA | **Manufacture** |
| 3M Deutschland GmbH<br>Healthcare Business<br>Carl-Schurz - Str. 1<br>41453 Neuss<br>Germany | **Control of Sterilization**<br>**EU Representative**<br>**Secondary Packaging** |
| 3M Deutschland GmbH<br>Health Care Business<br>Plant Kamen<br>Edisonstraβe 6<br>59174 Kamen<br>Germany | **Manufacture** |

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**Minnesota**
**55144**
**USA**

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| 3M Company<br>10351 West 70th Street<br>Eden Prairie<br>Minnesota 55344<br>USA | **Manufacture** |
| 3M Company<br>5400 Paris Road<br>Columbia<br>Missouri<br>65202<br>USA | **Manufacture** |
| 3M Company<br>601 22nd Ave. South<br>Brookings<br>South Dakota 57006<br>USA | **Gamma Sterilization**<br>**Manufacture** |

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**Supplementary Information to CE 00493**

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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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| 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™ Curos™ Disinfecting Caps, Tips, and Cap Strips |

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

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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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**No.** **CE 00493**

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**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

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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