

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: **2020-07-10**

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

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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.

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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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™ Curoso™ Disinfecting Caps, Tips, and Cap Strips

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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

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