

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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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.

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

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Supplementary Information to CE 00493

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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™ Curosurf™ 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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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:

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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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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 Edumex S. A. De C. V. 6620 Oriente Calle Ramón Rivera Lara Cd. Juárez Chihuahua 32605 Mexico	Manufacture
3M Health Care Limited Derby Road Loughborough Leicestershire LE11 5SF United Kingdom	Manufacture
ASO LLC 300 Sarasota Center Boulevard Sarasota Florida 34240 USA	Control of Sterilization Manufacture

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Subcontractor:	Service(s) supplied
Benchmark Electronics Inc. Minnesota Division, Winona location 4065 Theurer Blvd. Winona MN 55987 USA	Manufacture
BGS Beta-Gamma-Service GmbH & Co. KG Fritz-Kotz-Straße 16 51674 Wiehl Germany	Gamma Sterilization
BGS Beta-Gamma-Service GmbH & Co.KG John-Deere-Straße 3+1 76646 Bruchsal Germany	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	Gamma Sterilization
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	ETO Sterilization Gamma Sterilization
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	Gamma Sterilization
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	ETO Sterilization
James Alexander Corporation 845 Route 94 Blairstown New Jersey 07825 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
Sterigenics UK Limited Seymour Link Road Woodthorpe, Mastin Moor Chesterfield S43 3FG United Kingdom	Gamma Sterilization
Sterigenics US, LLC 108 Lake Denmark Road Rockaway New Jersey 07866 USA	Gamma Sterilization
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization
Sterilization Services of Tennessee 2396 Florida Street Memphis Tennessee 38109 USA	ETO Sterilization
STERIS Applied Sterilization Technologies (Formerly Synergy Health Applied Sterilization Technologies) Moray Road, Elgin Industrial Estate Swindon SN2 8XS UK	Gamma Sterilization

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Service(s) supplied

Suzhou Avon Textile Co., Ltd.
Yuanhe Town
Xiangcheng Region
215133 Suzhou, Jiangsu Province
People's Republic of China

**Control of Sterilization
Manufacture**

Synergy Health Sterilisation UK Ltd
(Synergy Health - AST - Bradford)
Roydsdale Way
Euroway Industrial Estate
Bradford
BD4 6SE
United Kingdom

Gamma Sterilization

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