

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 02242**

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 II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **1999-02-12**Date: **2020-09-21**Expiry Date: **2024-05-26**

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Page 1 of 7

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.

Certificate No: CE 02242

## Certificate Scope:

**The design and manufacture of electrosurgical plates, sterile medicated drapes, sterile medicated transparent film dressings, ethylene oxide gas sterilizers and cartridges, temperature monitoring sensors and controller, pressure infusion regulators, blood/fluid warming units and sterile disposable sets for infusion, fluid warming units and sterile disposable sets for irrigation, and patient warming units.**

**The design and manufacture of sterile wound dressings (non-medicated):**

- adhesive foam
- non-adhesive foam
- hydrocolloid
- alginate
- absorbent clear acrylic
- non adherent
- hydrogels

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Page 2 of 7

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NBOG code(s)	Device description	Intended Purpose
<b>Class III</b>		
---	3M™ Tegaderm™ CHG I.V. Securement Dressing	See CE 525600
---	3M™ Tegaderm™ CHG I.V. Port Dressing	See CE 525600
---	3M™ Tegaderm™ Antimicrobial Transparent Dressing	See CE 698003
---	3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing	See CE 698003
---	3M™ Ioban™ 2 Antimicrobial Incise Drapes	See CE 89073
---	3M™ Steri-Drape™ Ioban™ 2 Specialty Drapes	See CE 89073

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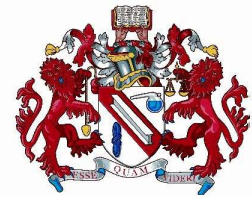
Expiry Date: **2024-05-26**

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Page 3 of 7

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NBOG code(s)	Device description	Intended Purpose
<b>Class IIb</b>		
MD 1104	3M™ Electrosurgical Plates	Dispersion electrodes used where electrosurgery is utilized to provide a safe return path for electrosurgical current

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Page 4 of 7

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<b>Class IIb</b>		
MD 1107	3M™ Steri-Vac™ Sterilizers/Aerators and Steri-Gas™ cartridges	Sterilize heat-and/or moisture-sensitive devices
MD 1101	3M™ Ranger™ Pressure Infusor	Provide pressure to I.V. solution bags when rapid infusion of liquids is required
MD 1101	3M™ Ranger™ Blood/Fluid Warming Unit	Intended to warm blood, blood product and liquids
MD 1302	3M™ Bair Hugger™ Warming Unit and Sensor	Intended to help prevent and treat hypothermia
MD 0301	3M™ Tegaderm™ Adhesive Foam Dressing	For use as a primary dressing for low to highly exuding, partial and full thickness dermal wounds.
MD 0301	3M™ Tegaderm™ Non-Adhesive Foam and Silicone Foam Dressing	For use as a primary dressing for low to highly exuding, partial and full thickness dermal wounds.

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Page 5 of 7

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<b>Class IIb</b>		
MD 0301	3M™ Tegaderm™ Hydrocolloid Dressing	For use on partial and full thickness derma ulcers, leg ulcers, superficial wounds, abrasions, first and second degree burns and donor sites
MD 0301	3M™ Tegaderm™ Alginate Dressing	For use on partial and full thickness wounds with moderate to heavy exudate
MD 0301	3M™ Tegaderm™ Absorbent Clear Acrylic Dressing	Indicated for partial and full thickness dermal ulcer
MD 0301	3M™ Tegaderm™ Contact, Non-Adherent Contact Layer	Intended for use directly over wounds
MD 0303	3M™ Tegaderm™ Hydrogel Wound Filler	Wound filler for non to minimally draining partial and full thickness dermal wounds

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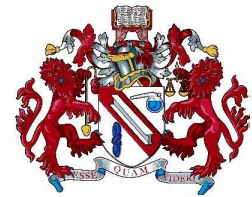
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Page 6 of 7

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NBOG code(s)	Device description	Intended Purpose
<b>Class IIa</b>		
MD 1302	3M™ Bair Hugger™ Temperature Monitoring System, Sensor and Control Unit	N/A
MD 0102	3M™ Ranger™ Blood/Fluid Warming Disposable Sets	N/A
MD 1101	3M™ Ranger™ Irrigation Fluid Warming Unit	N/A
MD 0102	3M™ Ranger™ Irrigation Fluid Warming System Disposable Sets	N/A

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Page 7 of 7

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