

# 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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Page 1 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.

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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Page 2 of 4

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