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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
3M Center
2510 Conway Avenue
Saint Paul
Minnesota
55144
USA

In respect of:

The manufacture of sterile transparent wound dressings, sterile non-adherent wound dressings, electronic stethoscopes and associated software, sterile skin staplers and sterile drapes (wound protector, isolation bag)

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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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 February 1995** Date: **17 August 2015** Expiry Date: **17 March 2020**

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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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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Supplementary Information to CE 00493

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Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of wound closures, wound dressings, drapes, barrier film, wraps, gauze pads and staple removers, patient warming/cooling 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 Devices Directive.

First Issued: **01 February 1995** Date: **17 August 2015** Expiry Date: **17 March 2020**

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