

Production Quality Assurance



No. CE 00493

Issued to:

**3M Healthcare
3M Center
Building 275
St. Paul
Minnesota
55144-1000
USA**

In respect of:

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

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on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: **1 Feb 1995**

Date: **20 Aug 2010**

Expiration Date: **17 Mar 2015**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

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Supplementary Information to CE 00493

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3M Healthcare
St. Paul
USA

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of clinical color change thermometers, wound closures, wound dressings, drapes, barrier film, wraps and gauze pads.

Those aspects of Annex V relating to metrology in the manufacture of clinical color change thermometers.

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.

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