

# 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**  
**3M Center**  
**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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **12 February 1999**

Date: **09 September 2016**

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.

Certificate No: CE 02242

## Certificate Scope:

**The design and manufacture of electrosurgical plates, sterile medicated drapes, gas sterilizers, 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, patient warming/cooling units and sterile disinfecting port protector devices.**

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

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

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