

# 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:

**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 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **1995-02-01**

Date: **2017-05-11**

Expiry Date: **2020-03-17**

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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 00493

## Certificate Scope:

**The manufacture of sterile transparent wound dressings, electronic stethoscopes and associated software, sterile skin staplers and sterile drapes (wound protector, isolation bag) and barrier film dressings.**

**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 Device Directive.**

First Issued: **1995-02-01**Date: **2017-05-11**Expiry Date: **2020-03-17**

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This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Production Quality Assurance

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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 Date: **2017-05-11**  
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Subcontractor:	Service(s) supplied
3M Company 10351 West 70th Street Eden Prairie Minnesota 55344 USA	<b>Sterile Manufacture</b>
3M Company 1617 North Front Street New Ulm Minnesota 56073 USA	<b>Manufacture</b>
3M Company 5400 Paris Road Columbia Missouri 65202 USA	<b>Sterile Manufacture</b>

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Subcontractor:	Service(s) supplied
3M Company 601 22nd Ave. South Brookings South Dakota 57006 USA	<b>Gamma Sterilization Sterile Manufacture</b>
3M Company 905 Adams Street SE Hutchinson Minnesota 55350 USA	<b>Manufacture</b>
3M Deutschland GmbH Healthcare Business Carl-Schurz - Str. 1 41453 Neuss Germany	<b>Control of Sterilization EU Representative Secondary packaging</b>

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Subcontractor:	Service(s) supplied
3M Deutschland GmbH Plant Kamen Edisonstrasse 6 59157 Kamen Germany	<b>Sterile Manufacture</b>
3M Edumex, S. A. De C. V. 6620 Oriente Calle Ramón Rivera Lara Cd. Juárez Chihuahua 32605 Mexico	<b>Sterile Manufacture</b>
3M Health Care Limited Derby Road Loughborough LE11 5SF United Kingdom	<b>Sterile Manufacture</b>

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Subcontractor:	Service(s) supplied
ASO LLC 300 Sarasota Center Boulevard Sarasota Florida 34240 USA	<b>Control of Sterilization</b> <b>Sterile Manufacture</b>
Benchmark Electronics Inc. Minnesota Division 4065 Theurer Boulevard Winona Minnesota 55987 USA	<b>Manufacture</b>
James Alexander Corporation 845 Route 94 Blairstown New Jersey 07825 USA	<b>Crucial Supplier</b>

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### Subcontractor:

### Service(s) supplied

Sterigenics US, LLC  
 108 Lake Denmark Road  
 Rockaway  
 New Jersey  
 07866  
 USA

**Gamma Sterilization**

Sterigenics US, LLC  
 10811 Withers Cover Park Drive  
 Charlotte  
 North Carolina 28278  
 USA

**Gamma Sterilization**

Sterigenics US, LLC  
 2400 Airport Road  
 Santa Teresa  
 New Mexico  
 88008  
 USA

**ETO Sterilization**

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Subcontractor:	Service(s) supplied
Sterilization Services of Tennessee, Inc 2396 Florida Street Memphis Tennessee 38109 USA	<b>ETO Sterilization</b>
STERIS Isomedix Services, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	<b>ETO Sterilization</b> <b>Gamma Sterilization</b>
STERIS Isomedix Services, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	<b>ETO Sterilization</b>

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Subcontractor:	Service(s) supplied
STERIS Isomedix Services, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	<b>Gamma Sterilization</b>
STERIS Isomedix Services, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	<b>ETO Sterilization</b>
Steris Isomedix Services, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	<b>Gamma Sterilization</b>

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Subcontractor:	Service(s) supplied
Suzhou Avon Textile Co., Ltd. Yuanhe Town Xiangcheng Region 215133 Suzhou, Jiangsu Province China	<b>Control of Sterilization Sterile Manufacture</b>
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	<b>Gamma Sterilization</b>
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	<b>Gamma Sterilization</b>

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Date	Reference Number	Action
01 February 1995		First Issue.
15 July 1997		Minor changes to certificate.
19 May 1998		Addition of powered and non-powered surgical instruments, sterilisers and incubators. Clarification in terms of drapes being sterile, and internal staplers expanded to skin staplers and bone staplers. Private label manufacture of TEGAGEN added. Limited aspects of sterility and metrology added in respect of TEMPADOT thermometers. Change of address from Brookings to St Paul and addition of 3M manufacturing sites as subcontractors.
14 August 1998		Addition of Griffiths Microscience and Isomedix sterilisation sites as subcontractors.
28 February 2000		Deletion of powered and non-powered surgical instruments, sterile drapes and bone staplers. Addition of electronic stethoscope and removal of private label manufacture of TEGAGEN through transfer to a separate certificate.

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Date	Reference Number	Action
22 December 2000		Reintroduction of sterile drapes omitted at the previous revision and remove TEMPADOT.
21 February 2001		Addition of Suzhou Avon Textile Co., Suzhou Medical College Institute of Radiation Technique and Horizon Medical.
07 June 2001		Addition of Bang & Olufsen Medicom as subcontractor for the manufacture of electronic stethoscopes.
18 March 2005		Renewal of certificate, correction to certificate address and subcontractors addresses, removal of Sterigenics International and Griffith MicroScience as subcontractors and change of subcontractor name from Horizon Medical to Avail Medical. Addition of sterile wraps.
14 June 2006		Addition of clinical change thermometers to the scope. Removal of 'defib pads' from the scope. Clarification of product families under the wound care scope. Consolidation of all 3M Healthcare's Annex V scopes into this certificate.
26 September 2006		Addition of Steris-Isomedix Services (Minneapolis) as a subcontractor for ETO Sterilisation.

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Date	Reference Number	Action
31 August 2007		<p>Removal of subcontractors 3M Canada Company (Canada), Steris Corporation (Canada), and Steris Corporation (Northborough). Removal of subcontractor Sterigenics (Various Locations) and replaced with Sterigenics (New Jersey).</p> <p>Change of service supplied from Manufacture to Sterile Manufacture for subcontractor 3M Health Care (Mexico).</p> <p>Change of service supplied from Sterilization to Gamma Sterilization for subcontractor 3M Health Care (South Dakota).</p> <p>Change of service supplied from Manufacture to Sterile Manufacture for subcontractor 3M Health Care (New Jersey).</p> <p>Change of name of Steris Corporation Isomedix Services to STERIS Isomedix Services, Inc and change of service supplied from Sterilization to Gamma Sterilization and ETO Sterilization (Texas).</p> <p>Change of name of Steris Corporation Isomedix Services to STERIS Isomedix Services, Inc and change of service supplied from Sterilization to ETO Sterilization (Minneapolis).</p>

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Date	Reference Number	Action
31 August 2007		Change of service supplied from Sterilization to ETO Sterilization for subcontractor Sterilization Services of Tennessee, Inc. Change of service supplied from Manufacture to Sterile Manufacture and from Sterilization to Control of Sterilization for subcontractor Suzhou Avon Textile Co Ltd. Change of service supplied from Manufacture to Sterile Manufacture and from Sterilization to Control of Sterilization for subcontractor Avail Medical Products, Inc.
06 May 2009	7358066	Addition of subcontractors; 'STERIS Isomedix Services, Inc, 1441 Don Haskins Drive, El Paso, Texas' for ETO Sterilisation and '3M Health Care, Germany' for EU Representative.
13 November 2009	7439685	Addition of subcontractors: 3M, (Hutchinson); STERIS Isomedix Services, Inc, North Facility, 1880 Industrial Drive, Libertyville, IL; STERIS Isomedix Services Inc, 2500 Commerce Drive, Libertyville, IL; and Sterigenics, North Carolina.
20 April 2010	7493225	Renewal and scope update to include Sterility Aspects of Article 12 Procedure Packs.
20 August 2010	7561312	Removal of sterilisers from scope.

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Date	Reference Number	Action
01 March 2011	7649238	Addition of significant subcontractor 3M Deutschland GmbH. Addition of activity 'Control of Sterilization' to significant subcontractor 3M Health Care Germany.
27 July 2011	7675314	Removal of significant subcontractors Avail Medical Products, Inc and Bang & Olufsen Medicom A/S. Addition of significant subcontractor Benchmark Electronics Inc. Scope extension to include associated software for electronic stethoscopes.
04 May 2012	7817507	Change of address to include Conway Ave. Addition of significant subcontractor ASO LLC. Addition of staple removers to scope.
24 September 2013	8036069	Removal of clinical color change thermometers from the Annex V sterility aspect. Removal of Those aspects of Annex V relating to metrology In the manufacture of clinical color change thermometers. Addition of patient warming/cooling blankets to the Annex V sterility aspect. Removal of subcontractor 3M Health Care New Jersey. Addition of subcontractor 3M Eden Prairie.

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Date	Reference Number	Action
11 March 2015	8284992	Certificate renewal. Modification of company name and address. Change of subcontractors names from 3M Health Care to 3M Company. Change of subcontractor 3M Deutschland GmbH address from Werk Kamen to Plant Kamen. Change of subcontractor name from 3M Health Care in Mexico to 3M Edumex, S. A. De C. V. Removal of subcontractor 3M Health Care, Flemington.
17 August 2015	8374749	Extension of scope to include securement devices.
12 November 2015	8426730	Addition of 3M Healthcare Limited Loughborough for sterile manufacture and addition of Synergy Bradford and Swindon for gamma sterilisation.
19 May 2016	8484455	Addition of significant contractor: Sterigenics US, Santa Teresa. Removal of scope expression "sterile non-adherent wound dressings".
11 May 2017	8710720	Extension of scope to include "barrier film dressings"; change of activities for 3M Neuss to include secondary packaging; addition of significant subcontractors 3M Columbia and James Alexander Corporation.

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