EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 725202 R000

Manufacturer: 3M Company

Address:
2510 Conway Ave.
Saint Paul
Minnesota
55144
USA

Single Registration Number: Not Available

EU Authorised Representative: 3M Deutschland GmbH

Address:
Healthcare Business
Carl-Schurz-Str. 1
41460 Neuss
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-02-08** Date: **2021-09-01** Expiry Date: **2026-02-07**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 725202 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile disinfecting port protector devices	Class IIa
Warming Blankets	Class Is
Self-Adherent Wrap	Class Is
Skin Closures	Class Is
Surgical Drapes	Class Is
Incise drapes	Class Is
Surgical drapes – other	Class Is
Skin staple removers	Class Is
Barrier Film	Class Is
Intravascular protection devices	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

First Issued: **2021-02-08** Date: **2021-09-01** Expiry Date: **2026-02-07**

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 725202 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-02-08	3154149	First issue.
Current	3424211	Supplemented - Addition of device group Class Is – Warming Blankets, Self-Adherent Wrap, Skin Closures, Surgical Drapes, Incise drapes, Surgical drapes – other, Skin staple removers, Barrier Film, Intravascular protection devices.

First Issued: **2021-02-08** Date: **2021-09-01** Expiry Date: **2026-02-07**

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 725202 R000

Date: **2021-09-01**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Sterigenics, US LLC 10821 Withers Cove Park Drive Charlotte North Caroline 28278 USA	**ETO Sterilization**
3M Company 905 Adams St. SE Hutchinson Minnesota 55350 USA	**Manufacture**
3M Company 5400 Paris Road Columbia Missouri 65202 USA	**Manufacture**
3M Company 601 22nd Ave. South Brookings South Dakota 57006 USA	**Manufacture** **Radiation (Gamma Sterilization)**
3M Company 10351 West 70th Street Eden Prairie Minnesota 55344 USA	**Manufacture**

...making excellence a habit.™

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 725202 R000

Date: **2021-09-01**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
3M Edumex S.A. de C.V. 6620 Oriente Calle Ramon Rivera Lara CD. Juarez Chihuahua 32605 Mexico	**Manufacture**
3M Health Care Limited Derby Road Loughborough Leicestershire LE11 5SF United Kingdom	**Manufacture**
Aphena Pharma Solutions – Maryland, LLC 7978 Industrial Park Road Easton Maryland 21601 USA	**Manufacture**
ASO, LLC 300 Sarasota Center Boulevard Sarasota Florida 34240 USA	**Manufacture**

...making excellence a habit.™

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 725202 R000

Date: **2021-09-01**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
BGS Beta-Gamma-Service GmbH & Co. KG Fritz-Kotz-Strasse 16 51674 Wiehl Germany	**Radiation (Gamma Sterilization)**
Isomedix Operations, Inc 1441 Don Haskins Drive El Paso Texas 79936 USA	**ETO Sterilization**
Isomedix Operations, Inc. 380 90th Ave NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**

...making excellence a habit.™

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 725202 R000

Date: **2021-09-01**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	**ETO Sterilization**
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**
Sterigenics UK Limited Seymour Link Road Woodthorpe, Mastin Moor Chesterfield S43 3FG United Kingdom	**Radiation (Gamma Sterilization)**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92878 USA	**Radiation (Gamma Sterilization)**

...making excellence a habit.™

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 725202 R000

Date: **2021-09-01**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	**Radiation (Gamma Sterilization)**
Sterilization Services of Tennessee 2396 Florida Street Memphis Tennessee 38109 USA	**ETO Sterilization**
Suzhou Avon Textile Co., Ltd. Yuanhe Town Xiangcheng Region 215133 Suzhou, Jiangsu Province People's Republic of China	**Manufacture**
Synergy Health Radeberg GmbH Juri-Gagarin-Strasse 15 Radeberg 01454 Germany	**Radiation (Gamma Sterilization)**
Synergy Health Sterilisation UK Ltd Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	**Radiation (Gamma Sterilization)**

...making excellence a habit.™

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 725202 R000

Date: **2021-09-01**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Synergy Health Sterilisation UK Ltd. Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	**Radiation (Gamma Sterilization)**
Synergy Health Sterilization UK Ltd. Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	**Radiation (Gamma Sterilization)**

...making excellence a habit.™

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.