By Royal Charter

EU Quality Assurance Certificate

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

MDR 725202 R001

Manufacturer: 3M Company

Address:
2510 Conway Avenue
Saint Paul
Minnesota
55144
USA

Single Registration Number: US-MF-000014086

EU Authorised Representative: 3M Deutschland GmbH

Address:
Healthcare Business
Carl-Schurz-Str. 1
41443 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):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-02-08**

Current Issue Date: **2026-04-30**

Starting Validity Date: **2026-04-30**

Expiry Date: **2031-02-07**

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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 Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile disinfecting port protector devices	Class IIa
Barrier film	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.	

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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.
2021-04-18	3424211	Supplemented – Addition of device group Class Is
2022-03-02	3486382	Supplemented – Addition of device group Barrier film and subcontractor Amended – Addition of Legal Manufacturer SRN number. Amended – Administrative change to correct EU representative address zip code Amended – Administrative change to remove 3M Company site. Amended – Subcontractor change Amended – Subcontractor address updated. Amended – Administrative error, Subcontractor missing after cert reissue. Subcontractor readded. Amended – Administrative, previous certificate history (Ref 3424211) missing amendment for addition of subcontractors
2022-07-13	3699536	Amended – Removal of subcontractors
2024-02-20	30107696	Amended – Addition of Ethylene oxide sterilisation subcontractor. Amended – removal of subcontractor names from certificate history.
2024-09-04	30232707	Amended – Removal of subcontractor and addition of new subcontractor.
2025-04-04	30380337	Amended – Addition of Ethylene oxide sterilisation subcontractor.

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Date	Reference Number	Action
2026-02-02	30631269	Re-issued – Certificate renewal. Amended – Change of manufacturer address formatting to align with manufacturer's other certificates (2510 Conway Avenue, Saint Paul, Minnesota, 55144, USA).
Current	30611747	Amended – Qualification of Parametric Release following EO sterilization for Class Is devices - Tube Securement Device and Steri-Drape Ophthalmic Drape, at existing subcontractor.

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