

# 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:** US-MF-000014086

**EU Authorised Representative:** 3M Deutschland GmbH

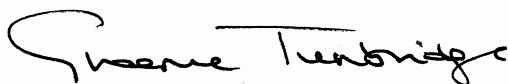
**Address:**

Health Care Business  
Carl-Schurz-Str. 1  
41453 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 Medical Devices

First Issued: **2021-02-08**

Date: **2022-07-13**

Expiry Date: **2026-02-07**

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

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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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