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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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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