

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 725050 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

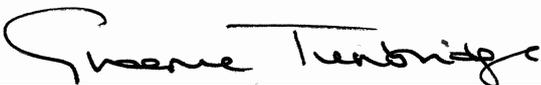
Address:

Health Care Business
Carl-Schurz-Str. 1
41453 Neuss
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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 Issue Date: **2022-09-12**

Current Issue Date: **2023-03-06**

Starting Validity Date: **2023-03-06**

Expiry Date: **2027-09-11**

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Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
3M™ Tegaderm™ CHG I.V. Securement Dressing	1657R	MDN 1204	Can be used to cover and protect catheter sites and to secure devices to skin. Common applications include central venous and arterial catheters, other intravascular catheters and percutaneous devices. The dressing is intended to reduce skin colonization and catheter colonization and to suppress regrowth of microorganisms commonly related to blood stream infections and to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.	Class III	60822384010100000000129Z
	1658R				
	1659R				
	1660R				
	1877R				
	1879R				

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Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
3M™ Tegaderm™ CHG Gel Pad Device	1664R	MDN 1204	Can be used to protect catheter sites. Common applications include protecting intravascular catheters and percutaneous devices. The dressing is intended to reduce skin colonization and catheter colonization and to suppress regrowth of microorganisms commonly related to bloodstream infections and to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.	Class III	0608223840101000000039AM

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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
2022-09-12	3154343	Issued
Current	3886233	Amended - Addition of new EO sterilisation cycle to existing subcontractor.



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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.

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A Member of the BSI Group of Companies.