EU Technical Documentation Assessment Certificate

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

MDR 725050 R000

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:
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: **2024-04-19**

Starting Validity Date: **2024-04-19**

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

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EU Technical Documentation Assessment Certificate

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

MDR 725050 R000

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 Chlorhexidine Gluconate I.V. Securement Dressing	1657R 1658R 1659R 1660R 1877R 1879R	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

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

MDR 725050 R000

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Intended purpose** (as per the IFU)	**Risk Classification**	**Basic UDI-DI**
3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad	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	06082238401010000000039AM

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EU Technical Documentation Assessment Certificate

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

MDR 725050 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
2022-09-12	3154343	Issued
2023-03-06	3886233	Amended - Addition of new EO sterilisation cycle to existing subcontractor.
Current	30107689	Amended – Addition of ethylene oxide sterilising subcontractor and update to labelling addition of "Chlorhexidine Gluconate" and removal of device for the Gel pad.

First Issue Date: **2022-09-12**

Current Issue Date: **2024-04-19**

Starting Validity Date: **2024-04-19**

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

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 725200 R000

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:
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 IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: **2022-10-06**

Current Issue Date: **2024-04-19**

Starting Validity Date: **2024-04-19**

Expiry Date: **2027-10-05**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 725200 R000

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
3M™ Tegaderm™ Antimicrobial Dressing (containing chlorhexidine gluconate)	See MDR 725198
Tegaderm CHG Dressing Family	See MDR 725050
Ioban™ 2 Antimicrobial Incise Drape	See MDR 725053

Class IIb	Intended purpose
Instruments for function exploration and therapeutic interventions	Indicated for hypothermic patients or normothermic patients for whom induced hypothermia or localized temperature therapy is clinically indicated and can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. Devices can be used with adult and pediatric patients. Intended to prevent and treat hypothermia and can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. Devices can be used with adult and pediatric patients.

First Issue Date: **2022-10-06**

Current Issue Date: **2024-04-19**

Starting Validity Date: **2024-04-19**

Expiry Date: **2027-10-05**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 725200 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
2022-10-06	3154149	Issued
2023-07-04	30000122	Supplemented – addition of Ioban™ 2 Antimicrobial Incise Drape devices
2024-03-06	30107148	Supplemented – addition of 3M™ Tegaderm™ Antimicrobial Dressing (containing chlorhexidine gluconate)
Current	30107694	Supplemented - Addition of instruments for function exploration and therapeutic interventions. Amended - Addition of sterilisation subcontractor

First Issue Date: **2022-10-06**

Current Issue Date: **2024-04-19**

Starting Validity Date: **2024-04-19**

Expiry Date: **2027-10-05**

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