

EU Technical Documentation Assessment Certificate

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

MDR 729706 R000

Manufacturer: Sofradim Production

Address:

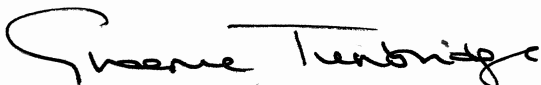
116 Avenue du Formans
Trévoux
01600
France

Single Registration Number: FR-MF-000012211

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 Global Regulatory & Quality

First Issue Date: **2022-09-20**

Current Issue Date: **2025-02-04**

Starting Validity Date: **2025-02-04**

Expiry Date: **2027-09-19**

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EU Technical Documentation Assessment Certificate

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

MDR 729706 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

Parietex™ optimized composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00003197J

Type (Codes as per (EU) 2017/2185): MDN 1104

Device Name	Shape	Size	Model
Parietex™ optimized composite mesh	Rectangular	15 x 10 cm	PCO1510X
		20 x 15 cm	PCO2015X
		25 x 20 cm	PCO2520X
		30 x 20 cm	PCO3020X
	Circular	Ø 9 cm	PCO9X
		Ø 12 cm	PCO12X
		Ø 15 cm	PCO15X
		Ø 20 cm	PCO20X
Parietex™ optimized composite mesh with pre-placed sutures	Rectangular	15 x 10 cm	PCO1510FX
		20 x 15 cm	PCO2015FX
		25 x 20 cm	PCO2520FX
		30 x 20 cm	PCO3020FX
	Circular	Ø 9 cm	PCO9FX
		Ø 12 cm	PCO12FX
		Ø 15 cm	PCO15FX
		Ø 20 cm	PCO20FX

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

MDR 729706 R000

Device Name	Shape	Size	Model
Parietex™ optimized composite mesh with open skirt	Rectangular	15 x 10 cm	PCO1510OSX
		20 x 15 cm	PCO2015OSX
		25 x 20 cm	PCO2520OSX
		30 x 20 cm	PCO3020OSX
	Circular	Ø 8 cm	PCO8OSX

Additional Information: Parietex™ optimized composite mesh contains collagen from porcine origin.



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Page 3 of 4

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 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

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

MDR 729706 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
2022-09-20	3217608	Issued
Current	30322426	Amended – Change of packaging component



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Page 4 of 4

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EU Quality Management System Certificate

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

MDR 729700 R000

Manufacturer: Sofradim Production

Address:

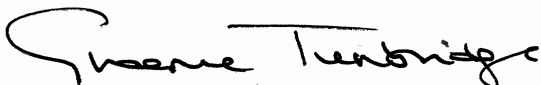
116 Avenue du Formans
Trévoux
01600
France

Single Registration Number: FR-MF-000012211

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: **2021-11-04**

Current Issue Date: **2024-02-27**

Starting Validity Date: **2024-02-27**

Expiry Date: **2026-11-03**

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EU Quality Management System Certificate

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

MDR 729700 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Parietene™ flat sheet mesh / Parietene™ lightweight mesh	See MDR 729726
Versatex™ Monofilament Mesh	See MDR 729727
Parietex™ Hydrophilic 2D Mesh	See MDR 729728
Parietex™ Hydrophilic 3D Mesh	See MDR 729728
Parietex™ Hydrophilic Anatomical Mesh	See MDR 729728
Symbotex™ Composite Mesh	See MDR 729711
Permacol™ Surgical Implant, porcine collagen-based matrix	See MDR 729721
Parietex™ Optimized Composite Mesh	See MDR 729706
Parietex™ Composite Ventral Patch	See MDR 729713
ProGrip™ Laparoscopic Self-Fixating Mesh	See MDR 729714
ProGrip™ Self-Gripping Polypropylene Mesh	See MDR 729715
ProGrip™ Self-Gripping Polyester Mesh	See MDR 729718
Parietene™ DS Composite Mesh	See MDR 729720
Dextile™ Anatomical Mesh	See MDR 729729
Parietex™ Composite Parastomal Mesh	See MDR 729709
Parietene™ Macroporous Mesh	See MDR 729722

First Issue Date: **2021-11-04**

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Expiry Date: **2026-11-03**

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Page 2 of 4

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EU Quality Management System Certificate

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

MDR 729700 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
2021-11-04	3217498	Issued.
2021-11-15	3578102	Supplemented – Addition of Parietex™ Hydrophilic 2D Mesh, Parietex™ Hydrophilic 3D Mesh, Parietex™ Hydrophilic Anatomical Mesh device. Amended – Addition of crucial supplier for Parietex™ Hydrophilic 2D Mesh, Parietex™ Hydrophilic 3D Mesh, Parietex™ Hydrophilic Anatomical Mesh
2022-02-21	3621310	Supplemented – addition of Symbotex Composite Mesh. Amended – Addition of crucial suppliers for Symbotex Composite Mesh.
2022-04-29	3681590	Supplemented – Addition of Permacol™ Surgical Implant. Amended – Addition of crucial suppliers for Permacol™ Surgical Implant. Amended – Correction of subcontractor name

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EU Quality Management System Certificate

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

MDR 729700 R000

Date	Reference Number	Action
2022-09-20	3657103	Supplemented – Addition of Parietex™ Optimized Composite Mesh, Parietex™ Composite Ventral Patch, ProGrip™ Laparoscopic Self-Fixating Mesh, and ProGrip™ Self-Gripping Polypropylene Mesh. Amended – Addition of crucial suppliers for Parietex™ Composite Ventral Patch, ProGrip™ Laparoscopic Self-Fixating Mesh, and ProGrip™ Self-Gripping Polypropylene Mesh.
2023-02-21	3787835	Supplemented – Addition of ProGrip™ Self-Gripping Polyester Mesh and Parietene™ DS Composite Mesh Amended – Administrative updates to previous history entries 3578102, 3621310, 3681590 and 3657103
2023-10-30	30033786	Supplemented – Addition of Dextile™ Anatomical Mesh
Current	30060130	Supplemented – Addition of Parietex™ Composite Parastomal Mesh and Parietene™ Macroporous Mesh

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Page 4 of 4

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EU MDR Declaration of Conformity

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Revision

C

Page 1 of 4

Medtronic

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Sofradim Production 116 avenue du Formans 01600 Trévoux France
Manufacturer SRN:	FR-MF-000012211
Authorized Representative:	N/A
Authorized Representative SRN:	N/A
Notified Body:	British Standard Institute (BSI) Group The Netherlands B.V. No. 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands
Conformity Assessment Certificate(s):	EU technical documentation assessment certificate: Annex IX Chapter I and III – MDR 729700 (<i>expires 03 November 2026</i>) Annex IX Chapter II MDR 729706 (<i>expires 19 September 2027</i>)
Conformity Assessment Procedure:	Annex IX Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation
Risk Class:	Class III
Classification Rule:	Rule 8 3 rd indent, Rule 8 7 th indent and Rule 18 from Annex VIII
Intended Purpose:	Parietex™ Optimized Composite Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries.

EU MDR Declaration of Conformity

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DOCMDR024

Revision

C

Page 2 of 4

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Statement:

We, Sofradim Production, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
Not applicable	Not applicable

Place: Trévoux, France

Name: Caroline DAURELLE for and on behalf of Sofradim Production

Title: Senior Regulatory Affairs Manager

Signature:



Date:

February 11, 2025

EU MDR Declaration of Conformity

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DOCMDR024

Revision

C

Page 3 of 4

Medtronic

Products Covered

Product Name	Medtronic Product Identifier	Basic-UDI-DI	EMDN code
	CFN		
Parietex™ Optimized Composite Mesh	PCO1510X	0763000B00003197J	P900204
	PCO2015X		
	PCO2520X		
	PCO3020X		
	PCO9X		
	PCO12X		
	PCO15X		
	PCO20X		
	PCO1510FX		
	PCO2015FX		
	PCO2520FX		
	PCO3020FX		
	PCO9FX		
	PCO12FX		
	PCO15FX		
	PCO20FX		
	PCO1510OSX		
	PCO2015OSX		
	PCO2520OSX		
	PCO3020OSX		
	PCO8OSX		

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DOCMDR024

Revision

C

Page 4 of 4

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Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Not applicable	Not applicable	Not applicable

Revision History

Revision	Date Effective	Description of Change
A	27 September 2022	Creation
B	17 January 2023	Removal of a # symbol before the basic UDI-DI
C	Refer to signature date	This document was reviewed following SCR150361 "Nelipak / Oliver Healthcare Packaging Tyvek® coating component change". New EC Certificate Annex IX Chapter II_#MDR 729706 was emitted on February 04, 2025. Update to new Template "D00009859 revision F"