

## EU MDR Declaration of Conformity (DoC)

<b>Manufacturer:</b>	Sofradim Production 116 avenue du formans 01600 Trévoux France
<b>Manufacturer SRN:</b>	FR-MF-000012211
<b>Authorized Representative:</b>	N/A
<b>Authorized Representative SRN:</b>	N/A
<b>Notified Body:</b>	British Standard Institute (BSI) Group The Netherlands B.V. No. 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands
<b>Conformity Assessment Certificate(s):</b>	EU technical documentation assessment certificate : <i>Annex IX Chapter I and III – MDR 729700 (expires 03 November 2026)</i> <i>Annex IX Chapter II – MDR 729713 (expires 19 September 2027)</i>
<b>Conformity Assessment Procedure:</b>	Annex IX Conformity Assessment based on a quality management system and on assessment of technical documentation
<b>Risk Class:</b>	Class III
<b>Classification Rule:</b>	Rule 8, 3 <sup>rd</sup> indent Rule 8, 7 <sup>th</sup> indent Rule 18
<b>Intended Purpose:</b>	Parietex™ Composite Ventral Patch is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary ventral hernia repair.

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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:**

September 27, 2022

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## Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI	EMDN code
	CFN		
Parietex™ composite ventral patch	PCO4VP	0763000B000032175	P900204
	PCO6VP		
	PCO8VP		

## Common Specification(s)

Not applicable

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