





Declaration of Conformity EXOSEAL® Vascular Closure Device  
PLM Number 12275834, Rev. 10

## DECLARATION OF CONFORMITY

**MDD:** We, Cordis Corporation, declare that the products covered in this Declaration of Conformity meet the provision of the Council Directive 93/42/EEC for Medical Devices as amended by 2007/47/EC and as transposed in the national laws of the Member States.

<b>Technical Documentation Number</b>	Not Applicable	
<b>Manufacturer's Name</b>	Cordis Corporation	
<b>Manufacturer's Address</b>	14201 North West 60th Avenue, Miami Lakes, FL 33014	
<b>Manufacturing Site (delete row if not applicable)</b>	Cardinal Health Mexico 244 S. De RL De CV Santiago Troncoso #808 Parque Industrial Salvacar Ciudad Juarez, Chihuahua C.P. 32574 México	
<b>Authorized Representative's Name and Address</b>	Cordis Cashel, Cahir Road, Cashel, Co. Tipperary, Ireland	
<b>Notified body's Name and Identification Number</b>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identification Number: 2797	
<b>CE Certificate Number</b>	CE 552677	
<b>Product Name</b>	EXOSEAL® Vascular Closure Device	
<b>Basic UDI-DI</b>	EXOSEAL® Vascular Closure Device	
<b>Product Code(s) and Description</b>	<b>Catalog Number</b>	<b>Description</b>
	EX500CE	EXOSEAL® 5F Vascular Closure Device
	EX600CE	EXOSEAL® 6F Vascular Closure Device
	EX700CE	EXOSEAL® 7F Vascular Closure Device
<b>Classification and Rule</b>	Class III, Per Annex IX, Rule Number 8 of Medical Device Directive (MDD 93/42/EEC as amended by Directive 2007/47/EC).	
<b>Single Registration Number</b>	Not Applicable.	
<b>Common Specifications</b>	Not Applicable.	
<b>Conformity Assessment</b>	In order to affix CE Marking, Cordis has followed the procedure relating to the EC Declaration of Conformity set out in Annex II, Clause 4 of Council Directive 93/42/EEC as amended by Directive 2007/47 EC.	
<b>GMDN Code</b>	58871	

SIGNATURE and DATE OF ISSUE			
This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.			
Place of Issue	14201 North West 60th Avenue, Miami Lakes, FL 33014		
Signature	 <small>Electronically signed by: Angel Estrada Reason: Approved Date: Feb 28, 2021 19:59 MST</small>	Date	Feb 28, 2021
Title/Position	Director, Quality and Regulatory Affairs Management		
Signature	 <small>Electronically signed by: Linda Ruedy Reason: Approved Date: Feb 26, 2021 20:06 PST</small>	Date	Feb 26, 2021
Title/Position	Director, Global Regulatory Affairs		

# 12275834 Rev 10 Exoseal VCD Declaration of Conformity

Final Audit Report

2021-03-01

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