Cordis

DECLARATION OF CONFORMITY

EU MDR: We, Cordis US Corp., declare that the products covered in this Declaration of Conformity meet the provision of the Medical Device Regulation (EU) 2017/745.

Technical Documentation Number	TD-PTA-001 and
Legal Manufacturer's Name	Cordis US Corp.
Legal Manufacturer's Address	14201 Northwest 60th Avenue Miami Lakes, FL 33014 USA
Manufactured under Contract by: (delete row if not applicable)	Nitinol Devices & Components Costa Rica, S.R.L. Coyol Free Zone, Buildings B14, B15 and B25 El Coyol, Alajuela 20102 Costa Rica
Authorized Representative's Name and Address	Cordis Cashel Cahir Road Cashel, Co. Tipperary Ireland
Notified body's Name and Identification Number	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identification Number: 2797
Certificate Numbers	EU Technical Document Assessment Certificate: MDR 759857 EU Quality Management System Certificate: MDR 759846
Product Name	Cordis AVIATOR PLUS Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter.
Basic UDI-DI	0705032000000000000022CB
Product Code(s) and Description	Refer to Table 1
Intended Purpose	The Cordis AVIATOR Plus PTA catheter is intended to impart an outward radial force on the luminal surface of the vessel wall to aid in restoring vascular patency. This device is also intended for post-dilatation of balloon-expandable and self-expanding stents.
Classification and Rule	Class III Non-Implantable (Annex VIII, Rule 6)

Digitally signed by Ostapciuc Alexandr
Date: 2023.07.08 12:33:32 EEST
Reason: MoldSign Signature
Location: Moldova

Single Registration Number	Legal Manufacturer SRN: US-MF-000020031	Authorized Rep SRN: IE-AR-000017793
Common Specifications	Not Applicable	
Conformity Assessment	To affix CE mark, Cordis US Corp has followed the procedure relating to the EU Declaration of Conformity set out in ANNEX IX of the Medical Device Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017.	
Device Nomenclature EMDN and GMDN Codes	**EMDN Code:** C010402020101, PTA Balloon Dilatation Catheters **GMDN Code:** 17184, Peripheral angioplasty balloon catheter, basic	

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	Linda Ruedy *Electronically signed by: Linda Ruedy* *Reason: Approved* *Date: Nov 3, 2022 16:23 PDT*	**Date**	
Title/Position	Sr. Director, Regulatory Affairs		
Signature	Matt Hedrick *Electronically signed by: Matt Hedrick* *Reason: Approved* *Date: Nov 3, 2022 11:27 EDT*	**Date**	
Title/Position	Sr. Director, Global Quality Operations		

ATTACHMENT 1

Product Code List	
Product Code	**Product Description**
424-4015W	4.0 mm x 15 mm
424-4020W	4.0 mm x 20 mm
424-4030W	4.0 mm x 30 mm
424-4040W	4.0 mm x 40 mm
424-4515W	4.5 mm x 15 mm
424-4520W	4.5 mm x 20 mm
424-4530W	4.5 mm x 30 mm
424-4540W	4.5 mm x 40 mm
424-5015W	5.0 mm x 15 mm
424-5020W	5.0 mm x 20 mm
424-5030W	5.0 mm x 30 mm
424-5040W	5.0 mm x 40 mm
424-5515W	5.5 mm x 15 mm
424-5520W	5.5 mm x 20 mm
424-5530W	5.5 mm x 30 mm
424-5540W	5.5 mm x 40 mm
424-6015W	6.0 mm x 15 mm
424-6020W	6.0 mm x 20 mm
424-6030W	6.0 mm x 30 mm
424-6040W	6.0 mm x 40 mm
424-7015W	7.0 mm x 15 mm
424-7020W	7.0 mm x 20 mm
424-7030W	7.0 mm x 30 mm
424-7040W	7.0 mm x 40 mm

Aviator Plus MDR DoC - Updated

Final Audit Report 2022-11-03

Created:	2022-11-02
By:	Ana Lopez (ana.lopez02@cordis.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA5Jm_UYL28C9k-hQdhb0RsR9vXgLaTVGD

"Aviator Plus MDR DoC - Updated" History

Document created by Ana Lopez (ana.lopez02@cordis.com)
2022-11-02 - 11:55:29 PM GMT

Document emailed to Linda Ruedy (linda.ruedy@cordis.com) for signature
2022-11-02 - 11:56:05 PM GMT

Document emailed to Vincent Hedrick (matt.hedrick@cordis.com) for signature
2022-11-02 - 11:56:05 PM GMT

Signer Vincent Hedrick (matt.hedrick@cordis.com) entered name at signing as Matt Hedrick
2022-11-03 - 3:27:48 PM GMT

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Linda Ruedy (linda.ruedy@cordis.com) verified identity with Adobe Acrobat Sign authentication
2022-11-03 - 11:23:17 PM GMT

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Signature Date: 2022-11-03 - 11:23:17 PM GMT - Time Source: server

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