

EU Technical Documentation Assessment Certificate

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

MDR 759857 R000

Manufacturer: Cordis US Corp.

Address:

14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

Single Registration Number: US-MF-000020031

EU Authorised Representative: Cordis Cashel

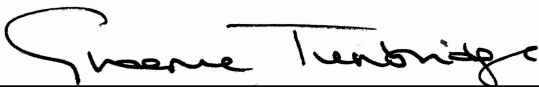
Address:

Cahir Road
Cashel
Co. Tipperary
Ireland

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: **2022-10-07**

Current Issue Date: **2022-10-07**

Starting Validity Date: **2022-10-07**

Expiry Date: **2027-10-06**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

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

MDR 759857 R000

Device Schedule:

Device Name: Cordis AVIATOR™ Plus Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter

Intended Purpose as per the Instructions for Use:

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.

Risk Classification: Class III

Type (Codes as per (EU) 2017/2185): MDN 1203

Basic UDI-DI: 07050320000000000000022CB



First Issue Date: **2022-10-07**

Current Issue Date: **2022-10-07**

Starting Validity Date: **2022-10-07**

Expiry Date: **2027-10-06**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

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

MDR 759857 R000

Model	Balloon Diameter	Balloon Length
424-4015W	4.0 mm	15 mm
424-4020W	4.0 mm	20 mm
424-4030W	4.0 mm	30 mm
424-4040W	4.0 mm	40 mm
424-4515W	4.5 mm	15 mm
424-4520W	4.5 mm	20 mm
424-4530W	4.5 mm	30 mm
424-4540W	4.5 mm	40 mm
424-5015W	5.0 mm	15 mm
424-5020W	5.0 mm	20 mm
424-5030W	5.0 mm	30 mm
424-5040W	5.0 mm	40 mm
424-5515W	5.5 mm	15 mm
424-5520W	5.5 mm	20 mm
424-5530W	5.5 mm	30 mm
424-5540W	5.5 mm	40 mm
424-6015W	6.0 mm	15 mm
424-6020W	6.0 mm	20 mm
424-6030W	6.0 mm	30 mm
424-6040W	6.0 mm	40 mm
424-7015W	7.0 mm	15 mm
424-7020W	7.0 mm	20 mm
424-7030W	7.0 mm	30 mm
424-7040W	7.0 mm	40 mm

First Issue Date: **2022-10-07**

Current Issue Date: **2022-10-07**

Starting Validity Date: **2022-10-07**

Expiry Date: **2027-10-06**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

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

MDR 759857 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
Current	3559754	Issued



First Issue Date: **2022-10-07**

Current Issue Date: **2022-10-07**

Starting Validity Date: **2022-10-07**

Expiry Date: **2027-10-06**

...making excellence a habit.™