



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 Starting Validity Date: 2022-10-07

Current Issue Date: **2022-10-07** Expiry Date: **2027-10-06** 

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Page 1 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.





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

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Page 2 of 4

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Model	Balloon Diameter	Balloon Length
424 <b>-</b> 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 <b>-</b> 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 <b>-</b> 5515W	5.5 mm	15 mm
424-5520W	5.5 mm	20 mm
424 <b>-</b> 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

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Page 3 of 4

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#### **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	China
Current	3559754	Issued	, 47,657

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

Current Issue Date: 2022-10-07

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Page 4 of 4

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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.