Cordis US Corp.
14201 North West 60th Avenue
Miami Lakes, Florida 33014
USA

29 September 2023

Notified Body Confirmation Letter

Reference: EU2023-607/655450

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Cordis US Corp.
14201 North West 60th Avenue
Miami Lakes, Florida 33014
USA

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.07 14:02:17 EEST
Reason: MoldSign Signature
Location: Moldova

SRN Number (if available): US-MF-000020031

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Avanti + Catheter Sheath Introducer 5.5 cm	Class IIa	N/A	CE 00340; NB 2797
Avanti+ Transradial Kit	Class IIa	N/A	CE 00340; NB 2797
Avanti + Catheter Sheath Introducer 7.5, 11 & 23 CM	Class III	N/A	CE 00340; NB 2797
Brite Tip CSI	Class III	N/A	CE 00340; NB 2797
Long Sheath/Long Sheath Set	Class III	N/A	CE 79729; NB 2797
Vista Brite Tip - Introducer Guide	Class III	N/A	CE 00340; NB 2797
Vessel Dilator	Class III	N/A	CE 00340; NB 2797
Cordis® INCRAFT® AAA Stent Graft System	Class III	N/A	CE 633652; NB 2797
OUTBACK® Elite Re-Entry Catheter	Class IIa	N/A	CE 00340; NB 2797
Cordis ADROIT™ Guiding Catheters	Class III	N/A	CE 598873; NB 2797
Cordis Steerable Guidewires, Cordis Diagnostic Guidewires and Cordis Short Transition Steerable Guidewires	Class III	N/A	CE 01439; NB 2797
StorQ Steerable Guidewire	Class IIa	N/A	CE 00340; NB 2797
SV .018 Guidewires	Class IIa	N/A	CE 00340; NB 2797
Powerflex™ Pro PTA Catheter	Class IIa	N/A	CE 00340; NB 2797
SABER™ .018 Percutaneous Transluminal	Class IIa	N/A	CE 556903; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Angioplasty (PTA) Dilatation Catheter			
SABER 0.35 PTA Catheter	Class IIa	N/A	CE 00340; NB 2797
Cordis S.M.A.R.T.® CONTROL® Nitinol Stent System	Class IIb - Implantable - Non WET	N/A	CE 00340; NB 2797
Cordis S.M.A.R.T.® Nitinol Stent System	Class IIb - Implantable - Non WET	N/A	CE 00340; NB 2797
Mynx Control Vascular Closure Device	Class III	N/A	CE 704856; NB 2797
Mynx Grip Vascular Closure Device	Class III	N/A	CE 617228; NB 2797
Cordis Emerald Diagnostic Guidewire	Class III	N/A	CE 01439; NB 2797
OptEase Retrievable Vena Cava Filter	Class III	N/A	CE 560271; NB 2797
OptEase Retrieval Catheter	Class III	N/A	CE 526303; NB 2797
INFINITI™ Angiographic Catheter	Class III	N/A	CE 636846; NB 2797
SUPER TORQUE™ Angiographic Catheter	Class III	N/A	CE 636846; NB 2797
SUPER TORQUE™ Plus Angiographic Catheter	Class III	N/A	CE 636846; NB 2797
SUPER TORQUE™ MB Angiographic Catheter	Class III	N/A	CE 636846; NB 2797
TEMPO™ AQUA Angiographic Catheter	Class III	N/A	CE 636846; NB 2797
TEMPO™ Angiographic Catheter	Class IIa	N/A	CE 636846; NB 2797
Palmaz GENESIS® Peripheral Stent on OPTA® PRO .035" Delivery System	Class IIb - Implantable - Non WET	N/A	CE 556903; NB 2797
Exoseal Vascular Closure Device	Class III	N/A	CE 552677; NB 2797
Cordis Palmaz® Blue™ .014" on Aviator Plus Stent System	Class IIb - Implantable - Non WET	N/A	CE 556903; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
PALMAZ® BLUE™ .018 Peripheral Stent System (Palmaz Blue on Slalom)	Class IIb - Implantable - Non WET	N/A	CE 556903; NB 2797
SaberX Radianz PTA Catheter	Class III	N/A	CE 556903; NB 2797
Brite Tip Radianz Guiding Sheath	Class III	N/A	CE 00340; NB 2797
Angiographic Catheterization Sets / Cardiac Multipack and Introducer System	Class III	N/A	CE 636846; NB 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
31 July 2023	Initial issue
29 September 2023	Addition of device OptEase Retrieval Catheter to the list Amendment of CE certificate number on Long Sheath/Long Sheath Set device