Digitally signed by Ostapciuc Alexandr
Date: 2024.07.22 12:20:31 EEST
Reason: MoldSign Signature
Location: Moldova

DEKRA

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

Your ref. NoC 2023-080, 2024-034
Our ref. MED/24-3835256 Rev3
Tel. +31 88 96 83 009
Fax +31 88 96 83 100
E-mail medical.nl@dekra.com

Digitally signed by Chicu Natalia
Date: 2024.12.09 10:31:38 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

26 March 2024

Subject: Notified Body Confirmation Letter

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, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 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 (dated 10 March 2021) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
SRN: US-MF-000004702

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 the Notified Body,

Amy Gravley
Project Manager

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:

Electrophysiology (EP) Products:

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
Dx Sterile Cables - DEKRA	Class I S	Not applicable	3812454CE01
Rx Sterile Cables - DEKRA	Class I S	Not applicable	3812454CE01
Blazer Dx-20 Diagnostic Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE15
Blazer II HTD Temperature Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer II Temperature Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer II XP Temperature Ablation Catheter & XP HTD	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer Open-Irrigated Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer Prime XP Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer Prime HTD Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaNav MiFi Open-Irrigated Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE37
IntellaNav MiFi XP Temperature Ablation Catheters	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaNav Open-Irrigated Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaNav ST Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaNav StablePoint Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaTip MiFi Open-Irrigated Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE37
IntellaTip MiFi XP Temperature Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Irrigation Tubing Set	Class II A	Not applicable	3812454CE01
MetriQ Irrigation Tubing Set	Class II A	Not applicable	3812454CE01

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
MetriQ Pump	Class II B	Not applicable	3812454CE01
Polaris X Steerable Diagnostic Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE15

Peripheral Interventions (PI) Products:

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
2D Helical-35 Fibered Platinum Coil	Class II B - Impl	Not applicable	3812454CE01
Athletis	Class II A	Not applicable	3812454CE01
Berenstein & Standard Occlusion Balloon Catheter (IIB)	Class II B	Not applicable	3812454CE01
Carotid Wallstent Monorail Carotid Endoprostesis	Class III - Impl	Not applicable	3812454CE01 3812454DE28
Charger PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Coil Pusher-16	Class II A	Not applicable	3812454CE01
Contour Embolization Particles	Class II B - Impl	Not applicable	3812454CE01
Coyote Balloon Dilatation Catheters MR & OTW	Class II A	Not applicable	3812454CE01
Coyote ES Monorail PTA Catheter	Class II A	Not applicable	3812454CE01
Coyote ES Over-the-Wire PTA Catheter	Class II A	Not applicable	3812454CE01
Direxion Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion HI-FLO Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion Fathom -16 System Pre-Loaded Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion Transend-14 System Pre-Loaded Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion HI-FLO Fathom-16 System Pre-Loaded Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion HI-FLO Transend-18 System Pre-Loaded Torqueable	Class II B	Not applicable	3812454CE01

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**
Microcatheter			
ELUVIA Over-The-Wire Drug-Eluting Vascular Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE38
Epic Over the WireSelf-Expanding Nitinol Vascular Stent with Delivery System	Class II B - Impl	Not applicable	3812454CE01
Equalizer Occlusion Balloon	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE11
Express Vascular LD Premounted Stent System	Class II B - Impl	Not applicable	3812454CE01
Express Vascular SD Premounted Stent System	Class II B - Impl	Not applicable	3812454CE01
Fathom 016 Steerable Guidewire	Class II A	Not applicable	3812454CE01
Fathom-14 Steerable Guidewire	Class II A	Not applicable	3812454CE01
Fibered Platinum Coils : VortXTM - 18 and VortXTM Diamond-18 Fibered Platinum Coils Complex Helical-18, Figure 8-18, Multi-Loop-18, straight-18 Fibered Platinum Coils	Class II B - Impl	Not applicable	3812454CE01
FloSwitch HP High Pressure Flow Control Device	Class II A	Not applicable	3812454CE01
Gateway PTA Balloon Catheter (Gateway)	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE10
Guider Softip XF Guide Catheter 5FR - 6FR - 7FR - 8FR	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE02
IDC Interlocking Detachable Coils	Class II B - Impl	Not applicable	3812454CE01
Innova Over-The-Wire Self-Expanding Stent System	Class II B - Impl	Not applicable	3812454CE01
Interlock - 35 Fibered IDC Occlusion System	Class II B - Impl	Not applicable	3812454CE01
Interlock Fibered IDC Occlusion System	Class II B - Impl	Not applicable	3812454CE01
Mustang PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
OptiCross 35	Class II A	Not applicable	3812454CE01
Peripheral Cutting Balloon (2cm Peripheral Cutting Balloon)	Class II A	Not applicable	3812454CE01

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
Microsurgical Dilatation Device			
Renegade Fiber Braided Microcatheter	Class II B	Not applicable	3812454CE01
Renegade Hi-Flo Fathom System	Class II B	Not applicable	3812454CE01
Renegade Hi-Flo Microcatheter Kits	Class II B	Not applicable	3812454CE01
Renegade Hi-Flo Microcatheter.	Class II B	Not applicable	3812454CE01
Renegade STC-18 Microcatheter	Class II B	Not applicable	3812454CE01
Rubicon Support Catheter 14, 18 & 35	Class II A	Not applicable	3812454CE01
Sterling Monorail PTA Balloon dilatation catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE10
Sterling Over-The-Wire PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Sterling SL Monorail PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Sterling SL Over-The-Wire PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Trueselect	Class II B	Not applicable	3812454CE01
VortX-35 Fibered Platinum Coil	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary Transhepatic Fully Covered Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary Transhepatic Fully Covered Stent System RMV	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary Transhepatic Partially Covered Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary Transhepatic Uncovered Stent System	Class II B - Impl	Not applicable	3812454CE01
Wallstent RP Endoprosthesis	Class II B - Impl	Not applicable	3812454CE01
Wallstent-Uni Endoprosthesis IIb	Class II B - Impl	Not applicable	3812454CE01
Wallstent-Uni Endoprosthesis III	Class III - Impl	Not applicable	3812454CE01 3812454DE25
XXL Balloon Dilatation Catheter (Vascular)	Class II A	Not applicable	3812454CE01
EMBOZENE Color-Advanced Microspheres	Class II B - Impl	Not applicable	3812454CE01
TANDEM Microspheres	Class III	Not applicable	3812454CE01 3812454DE44

Interventional Cardiology (IC) Products:

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
OptiCross 6 Coronary Imaging Catheter & OptiCross 6 HD Coronary Imaging Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE18
OptiCross Coronary Imaging Catheter & OptiCross HD Coronary Imaging Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE18
Comet II Pressure Guidewire	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE39
Comet Pressure Guidewire	Class III - Non-Impl	Comet II Pressure Guidewire	3812454CE01 3812454DE39
Disposable Pullback Sled	Class I S	Not applicable	3812454CE01
Emerge MONORAIL PTCA Dilatation Catheter Emerge Push MONORAIL PTCA Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE23
Emerge OVER-THE-WIRE PTCA Dilatation Catheter Emerge Push OVER-THE-WIRE PTCA Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE23
Encore 26 Advantage Kit	Class II A	Not applicable	3812454CE01
Encore 26 Inflation Device	Class I S/M	Not applicable	3812454CE01
Fluid Dock	Class I S	Not applicable	3812454CE01
GateWay Plus Y-Adapter	Class II A	Not applicable	3812454CE01
Guidezilla II Guide Extension Catheter	Class III - Non-Impl	Not applicable	3812454CE01
Guidezilla II LONG Guide Extension Catheter	Class III - Non-Impl	Not applicable	3812454CE01
Mamba and Mamba Flex Microcatheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE42
Maverick 2 Monorail PTCA	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE20
MDU5 PLUS Sterile Bag	Class I S	Not applicable	3812454CE01
NC Emerge PTCA Dilatation Catheter (MONORAIL)	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE34
NC Quantum Apex MONORAIL PTCA Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE12

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
NC Quantum Apex OVER-THE-WIRE PTCA Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE12
OptiCross 18 30 MHz Peripheral Imaging Catheter	Class II A	Not applicable	3812454CE01
PROMUS Elite Monorail Everolimus-Eluting Coronary Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE43
Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE06
Promus PREMIER Select MONORAIL Everolimus-Eluting Platinum Chromium Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE41
Rotablator Rotational Angioplasty System: Console	Class II A	Not applicable	3812454CE01
Rotablator RotaWire Guidewire with wireClip Torquer	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE24
RotaLink Advancer Catheter Advancing Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
RotaLink Burr Exchangeable Burr Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
RotaLink Plus Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
ROTAPRO Rotational Angioplasty System: Console	Class II A	Not applicable	3812454CE01
ROTAPRO Advancer Burr Advancing Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
ROTAPRO Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
Synergy MEGATRON MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE32
Synergy XD MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE46

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
Threader Monorail Micro-Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE33
Threader Over the Wire Micro-Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE33
Ultra ICE Plus 9 IntraCardiac Echo Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE18
WireClip Torquer	Class I S	Not applicable	3812454CE01
Wolverine Coronary Cutting Balloon MONORAIL Microsurgical Dilatation Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE40
SYNERGY MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	Class III - Impl	Synergy XD Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE32

Urology and Pelvic Health (Uro) Products:

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
UroMax Ultra Balloon Dilation Catheter	Class II A	Not applicable	3812454CE01
Encore 26 Inflation Device	Class I S/M	Not applicable	3812454CE01
Gateway Advantage Y-Adapter	Class II A	Not applicable	3812454CE01
Nephromax High Pressure Nephrostomy Balloon Catheter	Class II A	Not applicable	3812454CE01
Occluder Occlusion Balloon Catheter	Class II A	Not applicable	3812454CE01
SpaceOAR	Class III - Impl	Not applicable	3812454CE01 3812454DE47
SpaceOAR Vue	Class III - Imp	Not applicable	3812454CE01 3812454DE47

Endoscopy (Endo) Products:

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
Agile Esophageal Partially Covered Stent System, Agile Esophageal Fully Covered Stent System, Agile Esophageal Fully Covered removable (RMV) Stent System, Agile Esophageal Partially Covered Over-the-wire (OTW) Stent System, Agile Esophageal Fully Covered Over-the-wire (OTW) Stent System, Agile Esophageal Fully Covered removable (RMV) Over-the-wire (OTW) Stent System	Class II B - Impl	Not applicable	3812454CE01
Alliance II Integrated Inflation System (60ml Syringe/Gauge assembly)	Class I S/M	Not applicable	3812454CE01
Hurricane Rapid Exchange Dilatation Catheter	Class II A	Not applicable	3812454CE01
CRE RX Biliary Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
CRE Wireguided Balloon Dilatation Catheter	Class II B - Impl	Not applicable	3812454CE01
CRE Fixed Wire Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
CRE PRO Wireguided Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
CRE Pulmonary Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Encore 26 Inflation device	Class I S	Not applicable	3812454CE01
Extractor Pro Retrieval Balloon Catheter (RX, RX-S, XL)	Class I S/M	Not applicable	3812454CE01
Resolution 360 Clip Resolution Clip Device	Class I S	Not applicable	3812454CE01
Resolution 360 Ultra Clip	Class II B - Impl	Not applicable	3812454CE01
Rigiflex II Single Use Achalasia Balloon Dilator	Class I S	Not applicable	3812454CE01
Ultraflex Esophageal Stent System	Class II B - Impl	Not applicable	3812454CE01

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
(Covered & Uncovered) - Large Esophageal & Esophageal NG			
Ultraflex Tracheobronchial Stent System (Gen II - with green retention suture) - Non sterile	Class II B - Impl	Not applicable	3812454CE01
Ultraflex Tracheobronchial Stent System (Gen II - with green retention suture) - Sterile	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary RX Stent System Fully Covered	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary RX Stent System Fully Covered RMV	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary RX Stent System Partially Covered	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary RX Stent System Uncovered	Class II B - Impl	Not applicable	3812454CE01
WallFlex Enteral Stent With Anchor lock delivery System (Colonic)	Class II B - Impl	Not applicable	3812454CE01
WallFlex Enteral Stent With Anchor lock delivery System (Duodenal)	Class II B - Impl	Not applicable	3812454CE01
WallFlex Esophageal Fully Covered RMV Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Esophageal Fully Covered RMV Stent System Longer Loop	Class II B - Impl	Not applicable	3812454CE01
WallFlex Esophageal Fully Covered Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Esophageal Partially Covered Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Soft Enteral Stent With Anchor lock delivery System (Colonic)	Class II B - Impl	Not applicable	3812454CE01
WallFlex Soft Enteral Stent With Anchor lock delivery System (Duodenal)	Class II B - Impl	Not applicable	3812454CE01

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:

Interventional Cardiology (IC) Products:

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
iSLEEVE Introducer Set	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Sentinel Cerebral Protection System	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 717743, 26 May 2024, 2797

Urology and Pelvic Health (Uro) Products:

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
Gen 1 - Rezum System and Delivery Device Kit - Console	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Gen 1 - Rezum System and Delivery Device Kit - SUD	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Nephrostomy Catheter and Sets Percuflex Locking Loop Nephrostomy Catheter Percuflex Combination Stent/Nephrostomy Catheter Percuflex Locking Loop Catheter with Stent Percuflex Locking Loop All Purpose Drainage Catheter with Fader Tip Percuflex Locking Loop	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 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
Nephrostomy Catheter Kit Jinro Pigtail Nephrostomy Catheter Kit Jinro Pigtail Nephrostomy Catheter Jinro Pigtail Nephrostomy Catheter Replacement Kit			
Percuflex Urinary Diversion Stent Set	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Percuflex™ Ureteral Stent Percuflex™ Plus Ureteral Stent Contour™ Ureteral Stent Contour VL™ Variable Length Ureteral Stent Contour VL™ Variable Length Ureteral Stent Set Contour VL™ SureDrive™ Steerable Ureteral Stent Set Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set Polaris™ Ultra Ureteral Stent Polaris™ Loop Ureteral Stent Tria Firm Ureteral Stent Tria Soft Ureteral Stent	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Auriga™ XL 4007 Laser System			
Auriga™ 30 Laser System	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
GreenLight XPS Laser System	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
LightTrail Single Use & Reusable Use Laser Fibers	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
LightTrail TracTip Single Use Laser Fibers	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
LithoVue Empower Retrieval	Class II A	Not applicable	CE 616288, 26 May

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
Deployment Device			2024, 2797
Lithovue System	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Moxy Fiber GreenLight HPS Fiber GreenLight Fiber	Class II A	Not applicable	CE 616288, 26 May 2024, 2797

Endoscopy (Endo) Products:

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
Advanix Biliary Biliary Stent with NaviFlex RX Delivery System, Advanix Biliary Biliary Stent, Stent Delivery System, Biliary Stent Introducer	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Flexima Biliary Biliary Stent with Delivery System	Class II B - Impl	Not applicable	Flexima Biliary Biliary Stent with Delivery System
RX Biliary Biliary Stent with RX Delivery System	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Advanix Pancreatic Stent Kit, Advanix Pancreatic Stent, Naviflex RX Delivery System Pancreatic Stent Delivery System, Naviflex RX Pusher	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
AXIOS Stent and Delivery System	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
EXALT MODEL B SINGLE-USE BRONCHOSCOPE	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
EXALT Model D Single-Use	Class II A	Not applicable	CE 616288, 26 May

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**
Duodenoscope			2024, 2797
Habib EndoHPB Radiofrequency Ablation Catheter	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Hot Axios Stent and Electrocautery-Enhanced Delivery System	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
SpyGlass Discover Digital Catheter	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
SpyScope DS Access and Delivery Catheter & SpyScope DS II Access and Delivery Catheter	Class II A	Not applicable	CE 616288, 26 May 2024, 2797

Confirmation Letter Revision History

Date	**Certification Notice (No. + Ver.)**	**Action**
2024/01/30	3812454CN104.1	Initial issue
2024/02/06	NA	Addition of 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.
2024/02/20	N/A	Update to include EMBOZENE Color-Advanced Microspheres and TANDEM Microspheres as per MDR application received (NoC 2024-034) in the Peripheral Interventions (PI) Products table.
2024/03/25	N/A	Update to correct Tandem Microspheres to Class III. Update Embozene to correct certificate reference.