Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
(508) 683-4000
www.bostonscientific.com

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Boston Scientific Corporation
Manufacturer address and contact details	300 Boston Scientific Way Marlborough, MA 01752 USA
Single Registration Number (SRN) (if available)	US-MF-000004702

Authorised Representative name (if applicable)	Boston Scientific Limited
Authorised Representative address and contact details	Ballybrit Business Park Galway IRELAND
Single Registration Number (SRN) (if available)	IE-AR-000003840

Notified body name (if applicable)	DEKRA **X** See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Digitally signed by Ostapciuc Alexandr
Date: 2024.07.10 09:10:55 EEST
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Chicu Natalia
Date: 2024.12.09 10:32:41 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Notified body number (if applicable)	**X** See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	**X** See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	**X** See attached schedule
End date of extended validity/transition period	**X** See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements: **Not Applicable**

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement: **Not Applicable**

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

  Choose one applicable statement:

  - ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
  - **X A QMS in accordance with Article 10(9) MDR is in place.**
  - ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

  - The device(s) continue to comply with the AIMDD or MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

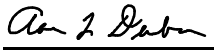
Full Company Name: **Boston Scientific Corporation**

Location: **MN, USA**

Name: **Aaron Dunbar**

Title: **Vice President, Quality Systems and Post Market**

Email: **Aaron.Dunbar@bsci.com**

Signature:  *Electronically signed by: Aaron Dunbar Reason: I am the Approver Date: Feb 21, 2024 15:56 CST*

Date: 21-Feb-2024

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Electrophysiology (EP) Products:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Dx Sterile Cables - DEKRA	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Rx Sterile Cables - DEKRA	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Blazer Dx-20 Diagnostic Catheter	3812454CE01 3812454DE15	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer II HTD Temperature Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer II Temperature Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer II XP Temperature Ablation Catheter & XP HTD	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer Open-Irrigated Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer Prime XP Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer Prime HTD Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
IntellaNav MiFi Open-Irrigated Ablation Catheter	3812454CE01 3812454DE37	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaNav MiFi XP Temperature Ablation Catheters	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaNav Open-Irrigated Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaNav ST Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaNav StablePoint Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaTip MiFi Open-Irrigated Ablation Catheter	3812454CE01 3812454DE37	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaTip MiFi XP Temperature Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Irrigation Tubing Set	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
MetriQ Irrigation Tubing Set	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
MetriQ Pump	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Polaris X Steerable Diagnostic Catheter	3812454CE01 3812454DE15	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Peripheral Interventions (PI) Products:

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
2D Helical-35 Fibered Platinum Coil	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Athletis	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Berenstein & Standard Occlusion Balloon Catheter (IIB)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Carotid Wallstent Monorail Carotid Endoprostesis	3812454CE01 3812454DE28	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Charger PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Coil Pusher-16	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Contour Embolization Particles	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Coyote Balloon Dilatation Catheters MR & OTW	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-2028	Not applicable
Coyote ES Monorail PTA Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-2028	Not applicable
Coyote ES Over-the-Wire PTA Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31Dec-2028	Not applicable
Direxion Torqueable Microcatheter Direxion HI-FLO Torqueable	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

[4] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Microcatheter Direxion Fathom -16 System Pre-Loaded Torqueable Microcatheter Direxion Transend-14 System Pre-Loaded Torqueable Microcatheter Direxion HI-FLO Fathom-16 System Pre-Loaded Torqueable Microcatheter Direxion HI-FLO Transend-18 System Pre-Loaded Torqueable Microcatheter						
ELUVIA Over-The-Wire Drug-Eluting Vascular Stent System	3812454CE01 3812454DE38	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Epic Over the WireSelf-Expanding Nitinol Vascular Stent with Delivery System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Equalizer Occlusion Balloon	3812454CE01 3812454DE11	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Express Vascular LD Premounted Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Express Vascular SD Premounted Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Fathom 016 Steerable Guidewire	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Fathom-14 Steerable Guidewire	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Fibered Platinum Coils : VortXTM -18 and VortXTM Diamond-18 Fibered Platinum Coils Complex Helical-18, Figure 8-18,	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Multi-Loop-18, straight-18 Fibered Platinum Coils						
FloSwitch HP High Pressure Flow Control Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Gateway PTA Balloon Catheter (Gateway)	3812454CE01 3812454DE10	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Guider Softip XF Guide Catheter 5FR - 6FR - 7FR - 8FR	3812454CE01 3812454DE02	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IDC Interlocking Detachable Coils	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Innova Over-The-Wire Self-Expanding Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Interlock - 35 Fibered IDC Occlusion System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Interlock Fibered IDC Occlusion System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Mustang PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
OptiCross 35	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Peripheral Cutting Balloon (2cm Peripheral Cutting Balloon) Microsurgical Dilatation Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Renegade Fiber Braided Microcatheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Renegade Hi-Flo Fathom System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Renegade Hi-Flo Microcatheter Kits	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Renegade Hi-Flo Microcatheter.	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Renegade STC-18 Microcatheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Rubicon Support Catheter 14, 18 & 35	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Sterling Monorail PTA Balloon dilatation catheter	3812454CE01 3812454DE10	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Sterling Over-The-Wire PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Sterling SL Monorail PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Sterling SL Over-The-Wire PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Trueselect	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
VortX-35 Fibered Platinum Coil	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary Transhepatic Fully Covered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
WallFlex Biliary Transhepatic Fully Covered Stent System RMV	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
WallFlex Biliary Transhepatic Partially Covered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
WallFlex Biliary Transhepatic Uncovered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Wallstent RP Endoprosthesis	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Wallstent-Uni Endoprosthesis IIb	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Wallstent-Uni Endoprosthesis III	3812454CE01 3812454DE25	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
XXL Balloon Dilatation Catheter (Vascular)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Embozene Color-Advanced Microspheres	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
TANDEM Microspheres	3812454CE01 3812454DE44	26 May 2024 11 Mar 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Interventional Cardiology (IC) Products:

Identification of the device(s)[5] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
OptiCross 6 Coronary Imaging Catheter & OptiCross 6 HD Coronary Imaging Catheter	3812454CE01 3812454DE18	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
OptiCross Coronary Imaging Catheter & OptiCross HD Coronary Imaging Catheter	3812454CE01 3812454DE18	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Comet II Pressure Guidewire	3812454CE01 3812454DE39	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Comet Pressure Guidewire	3812454CE01 3812454DE39	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Comet II Pressure Guidewire
Disposable Pullback Sled	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Emerge MONORAIL PTCA Dilatation Catheter	3812454CE01 3812454DE23	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

[5] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Emerge Push MONORAIL PTCA Dilatation Catheter						
Emerge OVER-THE-WIRE PTCA Dilatation Catheter Emerge Push OVER-THE-WIRE PTCA Dilatation Catheter	3812454CE01 3812454DE23	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Encore 26 Advantage Kit	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Encore 26 Inflation Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Fluid Dock	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
GateWay Plus Y-Adapter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Guidezilla II Guide Extension Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Guidezilla II LONG Guide Extension Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Mamba and Mamba Flex Microcatheter	3812454CE01 3812454DE42	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Maverick 2 Monorail PTCA	3812454CE01 3812454DE20	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
MDU5 PLUS Sterile Bag	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
NC Emerge PTCA Dilatation Catheter (MONORAIL)	3812454CE01 3812454DE34	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
NC Quantum Apex MONORAIL PTCA Dilatation Catheter	3812454CE01 3812454DE12	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
NC Quantum Apex OVER-THE-WIRE PTCA Dilatation Catheter	3812454CE01 3812454DE12	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
OptiCross 18 30 MHz Peripheral Imaging Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
PROMUS Elite Monorail Everolimus-Eluting Coronary Stent System	3812454CE01 3812454DE43	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE06	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Promus PREMIER Select MONORAIL Everolimus-Eluting Platinum Chromium Stent System	3812454CE01 3812454DE41	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Rotablator Rotational Angioplasty System: Console	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Rotablator RotaWire Guidewire with wireClip Torquer	3812454CE01 3812454DE24	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
RotaLink Advancer Catheter Advancing Device	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
RotaLink Burr Exchangeable Burr Catheter	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
RotaLink Plus Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
ROTAPRO Rotational Angioplasty System: Console	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
ROTAPRO Advancer Burr Advancing Device	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
ROTAPRO Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Synergy MEGATRON MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE32	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Synergy XD MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE46	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Threader Monorail Micro-Dilatation Catheter	3812454CE01 3812454DE33	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Threader Over the Wire Micro-Dilatation Catheter	3812454CE01 3812454DE33	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Ultra ICE Plus 9 IntraCardiac Echo Catheter	3812454CE01 3812454DE18	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WireClip Torquer	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Wolverine Coronary Cutting Balloon MONORAIL Microsurgical Dilatation Device	3812454CE01 3812454DE40	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
SYNERGY MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE32	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Synergy XD Everolimus-Eluting Platinum Chromium Coronary Stent System

Urology and Pelvic Health (Uro) Products:

Identification of the device(s)[6] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
UroMax Ultra Balloon Dilation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Encore 26 Inflation Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Gateway Advantage Y-Adapter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Nephromax High Pressure Nephrostomy Balloon Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Occluder Occlusion Balloon Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
SpaceOAR	3812454CE01 3812454DE47	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
SpaceOAR Vue	3812454CE01 3812454DE47	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

[6] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Endoscopy (Endo) Products:

Identification of the device(s)[7] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
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	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

[7] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Alliance II Integrated Inflation System (60ml Syringe/Gauge assembly)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Hurricane Rapid Exchange Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE RX Biliary Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE Wireguided Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE Fixed Wire Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE PRO Wireguided Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE Pulmonary Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Encore 26 Inflation device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Extractor Pro Retrieval Balloon Catheter (RX, RX-S, XL)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Resolution 360 Clip Resolution Clip Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Resolution 360 Ultra Clip	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Rigiflex II Single Use Achalasia Balloon Dilator	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Ultraflex Esophageal Stent System (Covered & Uncovered) - Large Esophageal & Esophageal NG	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Ultraflex Tracheobronchial Stent System (Gen II - with green retention suture) - Non sterile	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Ultraflex Tracheobronchial Stent System (Gen II - with green retention suture) - Sterile	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary RX Stent System Fully Covered	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary RX Stent System Fully Covered RMV	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary RX Stent System Partially Covered	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary RX Stent System Uncovered	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Enteral Stent With Anchor lock delivery System (Colonic)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Enteral Stent With Anchor lock delivery System (Duodenal)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Esophageal Fully Covered RMV Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Esophageal Fully Covered RMV Stent System Longer Loop	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Esophageal Fully Covered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Esophageal Partially Covered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Soft Enteral Stent With Anchor lock delivery System (Colonic)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

WallFlex Soft Enteral Stent With Anchor lock delivery System (Duodenal)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Manufacturer Declaration_DEKRA

Final Audit Report 2024-02-21

Created:	2024-02-21
By:	Mary Fretland (Mary.Fretland@bsci.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAK3TAJ8zr-f2MFNkaECiMHmoXn7XPMrHL
Number of Documents:	1
Document page count:	19
Number of supporting files:	0
Supporting files page count:	0

"Manufacturer Declaration_DEKRA" History

Document created by Mary Fretland (Mary.Fretland@bsci.com)
2024-02-21 - 7:57:12 PM GMT

Document emailed to Aaron Dunbar (Aaron.Dunbar@bsci.com) for signature
2024-02-21 - 7:59:42 PM GMT

Email viewed by Aaron Dunbar (Aaron.Dunbar@bsci.com)
2024-02-21 - 9:43:30 PM GMT

Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-21 - 9:51:47 PM GMT

Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2024-02-21 - 9:53:07 PM GMT

Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2024-02-21 - 9:54:09 PM GMT

Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-21 - 9:56:11 PM GMT

Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2024-02-21 - 9:56:44 PM GMT

Aaron Dunbar (Aaron.Dunbar@bsci.com) has agreed to the terms of use and to do business electronically with Boston Scientific

2024-02-21 - 9:56:45 PM GMT

Document e-signed by Aaron Dunbar (Aaron.Dunbar@bsci.com)

Signing reason: I am the Approver

Signature Date: 2024-02-21 - 9:56:45 PM GMT - Time Source: server

Agreement completed.

2024-02-21 - 9:56:45 PM GMT