Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Boston Scientific Corporation

300 Boston Scientific Way
Marlborough
MA 01752
USA
SRN ID.: US-MF-000004702

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 3812454CN

Additional certificate: 3830129TD01, 2258731TD01, 3830530TD01, 3830850TD01, 3831050TD01, 3831192TD01, 3832167TD01, 2262439TD01, 3831571TD01, 3832142TD01, 3830129TD02, 3830129TD03, 3830129TD04, 3830129TD05, 3830129TD06
Authorized Representative: Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland.

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

Digitally signed by Chicu Natalia
Date: 2024.12.09 10:33:20 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **25 October 2022** Date: **29 October 2024** Expiry date**: 25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, Class Is) **Sterilization method: X-ray radiation**
Device Name: ACURATE neo2 Loading Kit

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, Class Is) **Sterilization method: EtO**
Device Name: wireClip Torquer

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, Class Is) **Sterilization method: X-Ray Irradiation**
Device Name: ACURATE Prime Loading Kit

General non-active non-implantable device used in health care and other non-active non-implantable devices (MDN1213, Class Is) **Sterilization method: Gamma Irradiation**
Device Name: Disposable Pullback Sled for Motordrive

General non-active non-implantable devices used in health care and other non-active non-implantable devices (MDN1214, Class Is) **Sterilization method:** E-Beam Irradiation
Device Name: MDU5 Plus Sterile Bag **Device Name:** Permanent Sled Bag

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters and related tools (MDN 1203, Class Is, Im) **Sterilization method: EtO**
Device Name: Encore 26 Inflation Device

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters and related tools (MDN 1203, Class IIa)
Device Name: Encore 26 Advantage Kit

Non-active non-implantable instruments (MDN 1208, Class IIa)

First Issued: **25 October 2022** Date: **29 October 2024** Expiry date**: 25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Device Name: GateWay PLUS Y-Adapter

Active non-implantable imaging devices utilizing non-ionizing radiation (NBOG MDA0202, Class IIa)
Device Name: AVVIGO Guidance System II
Device Name: AVVIGO+ Guidance System

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, Class IIa)
Device Name: iSLEEVE Introducer Set

Class III
Device Name: ACURATE neo2 Aortic Valve
Device Name: ACURATE neo2 Transfemoral Delivery System
Device Name: SYNERGY XD MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: SYNERGY MEGATRON MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: SYNERGY SHIELD MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: Maverick2 Monorail PTCA Dilatation Catheter
Device Name: ROTAWIRE Drive and wireClip Torquer
Device Name: Guidezilla II Guide Extension Catheter
Device Name: Guidezilla II LONG Guide Extension Catheter
Device Name: SENTINEL Cerebral Protection System
Device Name: Emerge MONORAIL PTCA Dilatation Catheter
Device Name: Emerge Push MONORAIL PTCA Dilatation Catheter
Device Name: Emerge OVER-THE-WIRE PTCA Dilatation Catheter
Device Name: Emerge Push OVER-THE-WIRE PTCA Dilatation Catheter
Device Name: NC Emerge Monorail PTCA Dilatation Catheter
Device Name: NC Quantum Apex Monorail PTCA Dilatation Catheter
Device Name: Promus PREMIER MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: Promus PREMIER MONORAIL Select Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: Promus ELITE MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: Ultra ICE Plus 9 MHz IntraCardiac Echo Catheter
Device Name: OptiCross Coronary Imaging Catheter
Device Name: OptiCross 6 Coronary Imaging Catheter
Device Name: OptiCross HD Coronary Imaging Catheter
Device Name: OptiCross 6 HD Coronary Imaging Catheter
Device Name: Wolverine Coronary Cutting Balloon MONORAIL Microsurgical Dilatation Device
Device Name: MAMBA Microcatheter

First Issued: **25 October 2022** Date: **29 October 2024** Expiry date**: 25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Device Name: MAMBA Flex Microcatheter
Device Name: Agent MONORAIL Paclitaxel-Coated PTCA Balloon Catheter
Device Name: Threader MONORAIL Micro-Dilatation Catheter
Device Name: Threader OVER-THE-WIRE Micro-Dilatation Catheter
Device Name: ACURATE Prime Aortic Valve
Device Name: ACURATE Prime Delivery System

First Issued: **25 October 2022** Date: **29 October 2024** Expiry date**: 25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Conditions for or limitations to the validity of this certificate:

- For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	25 October 2022	3812454CN100	First issue
1	14 November 2022	3812454CN101	Revised
2	30 November 2022	3812454CN101	Revised
3	14 December 2022	3812454CN101	Revised
4	20 March 2023	3812454CN102	Revised
5	3 May 2023	3812454CN102	Revised
6	16 May 2023	3812454CN102	Revised
7	5 June 2023	3812454CN103	Revised
8	16 June 2023	3812454CN103	Revised
9	25 August 2023	3812454CN103	Revised
10	21 September 2023	3812454CN104	Revised
11	1 November 2023	3812454CN104	Revised
12	12 January 2024	3812454CN105	Revised
13	19 January 2024	3812454CN105	Revised
14	12 February 2024	3812454CN106	Revised
15	28 February 2024	3812454CN106	Revised
16	13 May 2024	3812454CN108.2	Revised
17	22 May 2024	3812454CN109	Revised
18	5 August 2024	3812454CN111	Revised
19	29 October 2024	3812454CN114	Revised

First Issued: **25 October 2022** Date: **29 October 2024** Expiry date**: 25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396