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
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.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Principal Certification Manager

First Issued: 25 **October 2022** Date: **30 November 2022** 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):

Annex IX EU Quality Management System Certificate

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

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

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

Class III
ACURATE neo2 Aortic Valve ACURATE neo2 Transfemoral Delivery System SYNERGY XD Everolimus-Eluting Platinum Chromium Coronary Stent System SYNERGY MEGATRON Everolimus-Eluting Platinum Chromium Coronary Stent System Maverick2 Monorail PTCA Dilatation Catheter

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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

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