Number: 3830129TD01

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II 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

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: **25 October 2022** Expiry date**: 25 October 2027**

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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

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EU Technical Documentation Assessment Certificate

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

Class III	
Basic UDI-DI:01915060000000000000256N5 ACURATE neo2 Aortic Valve P070301030101, Stented biological aortic valves for percutaneous implant - valve tissue of animal origin use Models: SYM-SV23-004 SYM-SV25-004 SYM-SV27-004	*Intended Purpose:* The ACURATE *neo2* Aortic Valve, in combination with the ACURATE *neo2* Transfemoral Delivery System and ACURATE *neo2* Loading Kit, is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart Valve replacement therapy.
Basic UDI-DI: 01915060000000000000259NB ACURATE neo2 Transfemoral Delivery System P07038002, Cardiac valve transcatheter implant accessories Model: SYM-DS-010	

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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

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