

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:

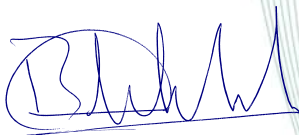
## 0344

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**

© Integral publication of this certificate and adjoining reports is allowed

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: 3830129TD01

# EU Technical Documentation Assessment Certificate

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

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

<b>Class III</b>	
<b>Basic UDI-DI:</b> 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	<i>Intended Purpose:</i> 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.
<b>Basic UDI-DI:</b> 01915060000000000000259NB ACURATE neo2 Transfemoral Delivery System P07038002, Cardiac valve transcatheter implant accessories Model: SYM-DS-010	

First Issued: 25 October 2022

Date: 25 October 2022

Expiry date: 25 October 2027

© Integral publication of this certificate and adjoining reports is allowed

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: 3830129TD01

# EU Technical Documentation Assessment Certificate

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

## 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

First Issued: **25 October 2022**

Date: **25 October 2022**

Expiry date: **25 October 2027**

© Integral publication of this certificate and adjoining reports is allowed

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