Boston Scientific Corporation
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EC Declaration of Conformity

Legal Manufacturer: **And SRN#**	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA SRN: US-MF-000004702
Design Site:	Boston Scientific Limited Ballybrit Business Park Galway IRELAND
Manufacturing Site(s):	Boston Scientific Limited Ballybrit Business Park Galway IRELAND
EU Authorized Representative: **And SRN#**	Boston Scientific Limited Ballybrit Business Park Galway IRELAND SRN: IE-AR-000003840
Product(s):	ACURATE *neo2*™ Aortic Valve System • ACURATE *neo2*™ Loading Kit Tech Doc File: 92486610 BUDI-DI: 01915060000000000000260MU
Risk Classification:	The ACURATE neo2 Loading Kit is classified as Class I Sterile in conformity with Annex VIII, Chapter III Rule 1.

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Notified Body:	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem NETHERLANDS Identification Number: 0344
Conformity Assessment Path:	Medical Device Regulation - 2017/745 Article 52 [7 a – Sterile]: Annex IX (Chp I & III) Conformity Assessment Based on a Quality Management System and Technical Documentation as per Annex II and III.
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.

Model Designations		
Catalogue/ REF#	**Description**	**Dimensions**
SYM-AC-010	**ACURATE neo2™ Loading Kit**	N/A

Certificates	
Certificate Name	**Certificate Numbers**
DEKRA EU Quality Management System Certification (IC Division – MDR)	#3830129CE01
DEKRA Management System Certificate - EN ISO 13485:2016	#3818536
DEKRA Management System Certificate - ISO 13485:2016	#3818535
DEKRA Management System Certificate - MDSAP	#3818534

Common Specifications:	Not Applicable

Additional EU Legislation Requiring Declarations of Conformity: Not Applicable

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All BSC manufactured products are released per Global SOP Active Release 92138090 provides the minimum requirements for active release of product which are distributed by Boston Scientific Corporation.

We declare that the product(s) identified are in conformance with all relevant provisions of the European Medical Device Regulation, MDR 2017/745, and with any other relevant Union legislation that provides for the issuance of an EU declaration of conformity. This EU Declaration of Conformity and all supporting information is issued and retained under the sole responsibility of Boston Scientific Corporation.

Signature, Date, Place of Issue:

Name: Mark Timlin

Title: Director, Quality

Signature: _____ 23-Nov-2022

Date Galway, Ireland

Name: Robbie Walsh

Title: Director, Regulatory Affairs

Signature: _____ 23/Nov/2022

Date Galway, Ireland

Note: For documents translated into a language other than English, refer to signatures and dates of issue from the accompanying English version.

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