By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737710 R000

Manufacturer: Boston Scientific Corporation

Address:
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Single Registration Number: US-MF-000004702

EU Authorised Representative: Boston Scientific Limited

Address:
Ballybrit Business Park
Galway
Ireland

Digitally signed by Ostapciuc Alexandr
Date: 2024.07.08 11:42:18 EEST
Reason: MoldSign Signature
Location: Moldova

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-12-16**

Current Issue Date: **2024-01-12**

Starting Validity Date: **2024-01-12**

Expiry Date: **2026-12-15**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
EKOS Endovascular Device	See MDR 746974
Transend Guidewires	See MDR 780705
Amplatz Super Stiff Guidewire	See MDR 778892
Back-Up Meier Steerable Guidewire	See MDR 778893

Class IIb	Intended purpose
Ultrasound Thrombolysis Control Unit	High frequency low power ultrasound device to facilitate the infusion of physician specified fluids, including procedural fluids and thrombolytics, into the pulmonary and/or peripheral vasculature of adults
Surgical Medical Aspirators	The device is intended to be used for the percutaneous removal of thrombus in the treatment of vascular disease.
Thrombectomy Suction Catheters	Intended for use with the AngioJet Console to break apart and remove thrombus.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Peripheral Angiography Devices	Class IIa
Peripheral Vascular Guidewires, Peripheral Angiography Guide Catheters	Class IIa
Percutaneous Drainage Systems – Other	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-12-16	3308482	Issued
2022-03-02	3623345	Supplemented – Addition of device Class IIa category "Peripheral angiography devices". Amended – Addition subcontractors.
2022-05-17	3693247	Supplemented – Addition of device Class IIb group "Ultrasound thrombolysis control unit" Amended – Addition of subcontractor for manufacture.
2022-12-15	3785636	Amended – Addition of subcontractors for Design, Manufacture and ETO Sterilization of Peripheral Vascular Guidewires. Removal of Subcontractors page. Administrative update to the Certificate History. Supplemented – Addition of device Class IIa category "Peripheral Vascular Guidewires".
2023-07-10	3849698	Supplemented - Addition of the Surgical Medical Aspirators device group.
2023-10-13	30005532	Supplemented – Addition of Transend Guidewires
Current	30035714	Supplemented – Addition of class III Amplatz Super Stiff Guidewire and Back-Up Meier Steerable Guidewire; class IIb group "Thrombectomy Suction Catheters"; addition of "Peripheral Angiography Guide Catheters" to category "Peripheral Vascular Guidewires" and class Is category "Percutaneous Drainage Systems – Other".

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