

EC CERTIFICATE

Number: **3812454CE01**

1/2

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Boston Scientific Corporation

**300 Boston Scientific Way
Marlborough, MA 01752
United States of America**

For the product category(ies)

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

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 EC-Directive which apply to them:

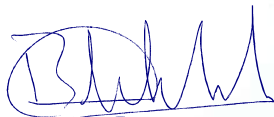
0344

Documents that form the basis of this certificate:

**Certification Notice 3812454CN, initially dated 1 July 2014
Addendum, initially dated 1 July 2014**

DEKRA hereby declares that the above-mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above-mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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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 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

EC CERTIFICATE

Number: 3812454CE01

2/2

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

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Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August 2012 concerning medical devices manufactured utilising tissue of animal origin. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory.

The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

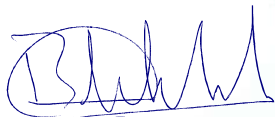
This certificate is valid until: **26 May 2024**

Issued for the first time: 1 July 2014

Revised: 21 December 2018

Reissued: 30 April 2020

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ADDENDUM

Belonging to certificate: **3812454CE01**

1/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

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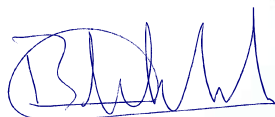
Boston Scientific Corporation

**300 Boston Scientific Way
Marlborough, MA 01752
United States of America**

This certificate covers the following location(s):

Location Code	Company name / address	Location Code	Company name / address
MAR2	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA	CR2	Boston Scientific Corporation 2546 First Street, Propark El Coyoil Alajuela Costa Rica
COR	Boston Scientific Limited Business & Technology Park Model Farm Rd Cork, Ireland	GAL	Boston Scientific Limited Ballybrit Business Park Galway, Ireland
COV	Boston Scientific Corporation 8 Industrial Drive Coventry, RI 02816 USA	KER	Boston Scientific International BV European Centre of Operations Vestastraat 6, 6468 EX Kerkrade, The Netherlands

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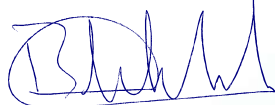
Boston Scientific Corporation

**300 Boston Scientific Way
Marlborough, MA 01752
United States of America**

This certificate covers the following location(s): continued

Location Code	Company name / address	Location Code	Company name / address
CR1	Boston Scientific Corporation 302 Parkway Global Park, Heredia Costa Rica	MAR	Boston Scientific Corporation 100 Boston Scientific Way Marlborough, MA 01752 USA
MG2	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA	SJ2	Boston Scientific Corporation 150 Baytech Drive San Jose, CA 95134 USA
SP	Boston Scientific Corporation 4100 Hamline Avenue N. St. Paul, MN 55112 USA	SPE	Boston Scientific Corporation 780 Brookside Drive Spencer, IN 47460 USA

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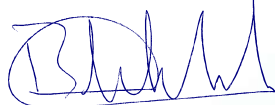
Boston Scientific Corporation

300 Boston Scientific Way
Marlborough, MA 01752
United States of America

This certificate covers the following location(s): continued

Location Code	Company name / address	Location Code	Company name / address
QUI	Boston Scientific Corporation Marina Bay Customer Fulfillment Center 500 Commander Shea Blvd Quincy, MA 02171 USA	ECU	Symetis SA Chemin de la Venoge 11 1024 Ecublens Switzerland
CHP	ACURATE Indústria e Comércio LTDA Chapécó Site Rua Apiuna, 520-D Cristo Rei Chapécó / SC – Brazil	BHM	ACURATE Indústria e Comércio LTDA BHM Site (Belo Horizonte Site) Avenida General David Sarnoff, 344 Lote 02 – Quadra 31A Cidade Industrial Contagem/MG – Brazil
PEN	Boston Scientific Medical Device (Malaysia) Sdn. Bhd. PMT 741, Persiaran Cassia Selatan 1 Taman Perindustrian Batu Kawan 14110 Bandar Cassia, Pulau Pinang, Malaysia		

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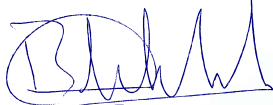
Boston Scientific Corporation

**300 Boston Scientific Way
Marlborough, MA 01752
United States of America**

Initial date: 1 July 2014

Revision date: 1 June 2020

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