EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 666431**

Issued To: **Biosense Webster, Inc.**
31 Technology Drive, Suite 200
Irvine
California
92618
USA

In respect of:

The design, development and manufacture of Sterile Cardiac Ablation Catheters, Electrophysiology Catheters, Ultrasound Catheters, Guiding Sheaths, tubing sets, non-Sterile connection cables, Irrigation Pumps and Radio Frequency (RF) Generators.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

[redacted]

Gar[redacted]

First Issued: **2017-01-06** Date: **2021-05-04** Expiry Date: **2024-05-26**

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Supplementary Information to CE 666431

Issued To:

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31 Technology Drive, Suite 200
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Number	Device Name	Intended Purpose per IFU
Class III		
---	DEFLECTABLE TIP	See CE 666433
---	AVAIL	See CE 666434
---	CARTO VIZIGO	See CE 678646
---	CELSIUS	See CE 666433
---	CELSIUS DS	See CE 666433
---	CELSIUS FLTR	See CE 666433
---	CELSIUS RMT	See CE 666433
---	CELSIUS RMT THERMOCOOL	See CE 666433
---	CELSIUS THERMOCOOL	See CE 666433
---	CRISTACATH	See CE 666433
---	DECANAV	See CE 666433
---	DEFLECTABLE BRAIDED TIP	See CE 666433
---	EZ STEER	See CE 666433
---	EZ STEER DS	See CE 666433
---	EZ STEER NAV	See CE 666433
---	EZ STEER NAV DS	See CE 666433
---	EZ STEER THERMOCOOL	See CE 666433
---	EZ STEER THERMOCOOL NAV	See CE 666433

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Class III		
---	FIXED ORTHOGONAL	See CE 666434
---	HALO XP	See CE 666433
---	ISMUS CATH	See CE 666433
---	ISMUS CATH WITH AUTO ID	See CE 666433
---	LASSO	See CE 666433
---	LASSO 2515	See CE 666433
---	LASSO 2515 NAV	See CE 666433
---	LASSO 2515 NAV eco	See CE 666433
---	LASSO NAV	See CE 666433
---	MYOSTAR INJECTION CATHETERS	See CE 666435
---	NAVISTAR	See CE 666433
---	NAVISTAR DS	See CE 666433
---	NAVISTAR RMT	See CE 666433
---	NAVISTAR RMT THERMOCOOL	See CE 666433
---	NAVISTAR THERMOCOOL	See CE 666433
---	NOGASTAR	See CE 666433
---	PARAHISIAN	See CE 666433

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Number	Device Name	Intended Purpose per IFU
Class III		
---	PENTARAY NAV	See CE 666436
---	PREFACE	See CE 666437
---	SOUNDSTAR	See CE 666438
---	THERMOCOOL SF	See CE 666433
---	THERMOCOOL SF NAV	See CE 666433
---	THERMOCOOL SMARTTOUCH	See CE 666433
---	THERMOCOOL SMARTTOUCH SF	See CE 666433
---	WEBSTER (Deflectable)	See CE 666433
---	WEBSTER (Fixed)	See CE 666434
---	WEBSTER COMPLI	See CE 666434
---	WEBSTER WITH AUTO ID	See CE 666433
---	WEBSTER WITH AUTO ID	See CE 666434
---	WEBSTER CS CATHETER WITH AUTO ID	See CE 666433
---	WEBSTER CS CATHETER WITH EZ STEER	See CE 666433
---	WEBSTER CS CATHETER WITH EZ STEER AND AUTO ID	See CE 666433
---	WEBSTER DUO-DECAPOLAR	See CE 666433
---	WEBSTER WITH AUTO ID	See CE 666433

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Number	Device Name	Intended Purpose per IFU
Class IIb		
35156	Radio-frequency Ablation System Generator	The RF Generator is indicated for use in conjunction with compatible catheters for cardiac ablation.
47487	TX Eco Cable	The TX eco Cable is used with Biosense Webster therapeutic catheters, CARTO 3 System, and RF Generator for catheter-based cardiac electrophysiological mapping and ablation to treat heart arrhythmias. The intended use of the TX eco Cable is to pass digitally processed signals from the compatible catheters to the CARTO 3 System V6.0 and later. The TX eco Cable communicates data from Biosense Webster Therapeutic Catheters to the CARTO 3 System and RF Generator.

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Number	Device Name	Intended Purpose per IFU
Class IIa		
MD 1101	Irrigation Pump, roller	---
MD 0106	Cardiac Tissue Ablation System Irrigation Tubing Set	---
MD 0106	Cardiac Mapping System Catheter, Oesophageal, Single Use	---

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 666431**

Date: **2021-05-04**

Issued To: **Biosense Webster, Inc.**
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Date	Reference Number	Action
06 January 2017	8649073	First issue.
08 March 2017	8691356	Certificate renewal.
30 June 2017	8748168	Added significant subcontractor, Stellartech Research as a manufacturer.
05 February 2018	8891433	Subcontractor name change from "Siemens Healthcare Ltd." to "Siemens Healthineers Ltd".
07 September 2018	8886197	Added significant subcontractors; Freudenberg Medical for control of sterilization and manufacture and Venusa de Mexico S. de R.L. de C.V. as a manufacture. Revised the scope wording by replacing "coronary" with "cardiac."
18 February 2019	7780555	Traceable to NB 0086.

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Date	Reference Number	Action
22 March 2021	9770009	Certificate renewal. Reduction of scope to remove 'Those aspects of Annex II related to securing and maintaining sterility in the manufacture of External reference devices.' Update to scope to include 'connection cables'. Addition of subcontractors 'Flextronics (Israel) Ltd., 2 Hamatechet St., Migdal Haemek, Israel', 'Sanmina - SCI Israel Medical Systems Ltd., Zone 5, Koren Industrial Park, Maalot, 24952, Israel', 'Siemens Medical Solutions USA, Inc, 22010 S.E. 51st Street, Issaquah, WA 98029, USA' and 'Cardinal Health Mexico 244 S de RL de CV, Santiago Troncoso 808, Parque Indutrial Salvarcar, Ciudad Juarez, Chihuahua, CP 32574, Mexico'. Removal of subcontractors 'Biosense Webster, Inc (Baldwin Park)', 'Cordis de Mexico S.A. de C.V. (Chihuahua)', 'Lake Region Medical, (El Paso)', 'Sterigenics Belgium (Petit-Rechain) SA' and 'Siemens Medical Solutions USA, Inc (Mountain View)'. Subcontractors name changes ('Freudenberg Medical' to 'Freudenberg Medical, LLC'; 'Sterigenics International, Inc' to 'Sterigenics US, LLC' (Los Angeles); 'Sterigenics US, Inc' to 'Sterigenics US, LLC' (Santa Teresa); 'STERIS ISOMEDIX Services, Inc' to 'Isomedix Operations, Inc'). Administrative address changes (Biosense Webster (Israel); Biosense Webster (Mexico), Siemens Healthineers Ltd; Sterigenics US, LLC (Los Angeles)) to align with vendor's ISO 13485 certificate. Addition of product supplementary information table.
04 May 2021	3309702	Change Legal Manufacturer address to 31 Technology Drive, Suite 200, Irvine, California 92618 USA.

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
11 October 2022	3682053	Administrative changes to the List of Significant Subcontractors and to the Supplementary Information table: Removal of ARMM, Inc and Cordis Corporation from the List of Significant Subcontractors; addition of Control of Sterilization to Cardinal Health Mexico List of Services; removal of Control of Sterilization from Freudenberg Medical List of Services; addition of Control of Sterilization to Venusa de Mexico List of Services. Removal of DE certificates CE 666433 and CE 666434 from the Supplementary Information table.
12 June 2023	3616980	Removal of subcontractor for design of sterile cardiac ablation catheters and electrophysiology catheters, tubing sets, irrigation pumps, RF generators, Guiding Sheaths and TX eco cable and manufacturing of sterile cardiac ablation catheters and electrophysiology catheters. Reintroduction of DE certificates CE 666433 and CE 666434 to the Supplementary Information table in the context of EU 2023/607.

Inspiring trust for a more resilient world.

12 June 2023

Biosense Webster, Inc.
31 Technology Drive, Suite 200
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92618
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 666431	93/42/EEC Annex II excluding Section 4	3616980	Removal of subcontractor for design of sterile cardiac ablation catheters and electrophysiology catheters, tubing sets, irrigation pumps, RF generators, Guiding Sheaths and TX eco cable and manufacturing of sterile cardiac ablation catheters and electrophysiology catheters. Reintroduction of DE certificates CE 666433 and CE 666434 to the Supplementary Information table in the context of EU 2023/607.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

[redacted]

Graeme Tunbridge
Senior Vice President, Medical Devices