

# 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):



Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2017-01-06**

Date: **2021-05-04**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 666431

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**31 Technology Drive, Suite 200**  
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**USA**

| Number           | Device Name             | Intended Purpose per IFU |
|------------------|-------------------------|--------------------------|
| <b>Class III</b> |                         |                          |
| ---              | 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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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|------------------|-----------------------------|--------------------------|
| <b>Class III</b> |                             |                          |
| ---              | 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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|------------------|---|--------------------------|
| <b>Class III</b> |   |                          |
| ---              | 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   |
|------------------|---|--|
| <b>Class IIb</b> |   |  |
| 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 |
|------------------|--|--------------------------|
| <b>Class IIa</b> |  |                          |
| 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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| 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 Industrial 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  |
|---|------------------|---|
| <b>Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3</b> |                  |   |
| 11 October 2022   | 3682053          | Administrative changes to the List of Significant Subcontractors and to the Supplementary Information table:<br>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.<br>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.<br>Reintroduction of DE certificates CE 666433 and CE 666434 to the Supplementary Information table in the context of EU 2023/607.   |

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12 June 2023

Biosense Webster, Inc.  
31 Technology Drive, Suite 200  
Irvine  
California  
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 26<sup>th</sup> 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.<br><br>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,



Graeme Tunbridge  
Senior Vice President, Medical Devices