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

Your ref.	Email (Date: 14/06/2023) Email (Date: 29/06/2023)
Our ref.	MED/23-028i Rev.1
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Arnhem, 4 July 2023

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Biosense Webster Inc.
31 Technology Drive,
Suite 200, Irvine,
CA 92618,
USA
SRN Number: US-MF-000014219

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2

identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

[redacted]

Mr. Meir Harpaz
Project Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
QDOT MICRO Uni-directional and Bi-directional Catheters Basic UDI-DI: 08468350a0026F7	Class III	N/A	Certificate #1; 3826381DE02, NB# 0344 Certificate #2; 3826381CE01, NB #0344
HELIOSTAR BALLOON ABLATION CATHETER Basic UDI-DI: 08468350a0027F9	Class III	N/A	Certificate #1; 3826381DE01, NB# 0344 Certificate #2; 3826381CE01, NB #0344
CARTO OCTARAY Mapping Catheter with TRUEref Technology Basic UDI-DI: 08468350a0031EY	Class III	N/A	Certificate #1; 3826381DE04, NB# 0344 Certificate #2; 3826381CE02, NB #0344

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 WEBSTER WEBSTER COMPLI WEBSTER CS WEBSTER Duo-Decapolar CRISTACATH ISMUS HALO XP DECANAV AVAIL PARAHISIAN Catheter Basic UDI-DI: 08468350a0014EY	Class III	N/A	Certificate #1; 666433, NB# 2797 Certificate #2; 666434, NB #2797
Device 2 Celsius NaviStar Catheter EZ Steer EZ Steer NAV Bi-Directional Catheter Basic UDI-DI: 08468350a0016F4	Class III	N/A	Certificate #; 666433, NB# 2797
Device 3 NaviStar RMT Celsius RMT Catheter Basic UDI-DI: 08468350a0017F6	Class III	N/A	Certificate #; 666433, NB# 2797
Device 4 NAVISTAR THERMOCOOL CELSIUS THERMOCOOL Catheter EZ STEER	Class III	N/A	Certificate #; 666433, NB# 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
THERMOCOOL NAV EZ STEER THERMOCOOL Bi-Directional Catheter Basic UDI-DI: 08468350a0022EX			
Device 5 NAVISTAR RMT THERMOCOOL CELSIUS RMT THERMOCOOL Catheter Basic UDI-DI: 08468350a0021EV	Class III	N/A	Certificate #; 666433, NB# 2797
Device 6 SOUNDSTAR 3D SOUNDSTAR eco 10F SOUNDSTAR eco 10FG SOUNDSTAR eco 8F SOUNDSTAR eco 8FG Diagnostic Ultrasound Catheter Basic UDI-DI: 08468350a0028FB	Class III	N/A	Certificate #; 666438, NB# 2797
Device 7 CARTO VIZIGO Catheter Basic UDI-DI: 08468350a0023EZ	Class III	N/A	Certificate #; 678646, NB# 2797
Device 8 nGEN Generator Basic UDI-DI: 08468350a0007F3	Class IIb	N/A	Certificate #; 666431, NB# 2797
Device 9 nGEN Pump	Class IIa	N/A	Certificate #; 666431, NB# 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 08453840a0014CW			
Device 10 SMARTABLATE Irrigation Tubing Set Basic UDI-DI: 08468350a0005EX	Class IIa	N/A	Certificate #; 666431, NB# 2797
Device 11 TX eco Cable Basic UDI-DI: 08468350a0025F5	Class IIb	N/A	Certificate #; 666431, NB# 2797

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2023/06/27	3826381CN29.1	Initial issue
2023/06/27	3826381CN29.1	Update table 2