Number: 3903009TD07

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Biosense Webster, Inc

31 Technology Drive, Suite 200
Irvine, CA 92618
USA
SRN ID.: US-MF-000014219

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 EU- Regulation which apply to them:

0344

Supplement to certificate: 3826381CN

Authorized Representative: Biosense Webster, A Division of Johnson & Johnson Medical NV/SA, Leonardo da Vincilaan 15, 1831 Diegem, Belgium

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

[redacted]

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **31-07-2023** Date: **31-07-2023** Expiry date: **01-07-2028**

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 www.dekra-product-safety.com Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Class III	
Basic UDI (Celsius): 08468350a0016F4 **Device Name:** Celsius™ Catheter **Type: C020301 - Cardiac Tissue Ablation Electrocatheters, Radiofrequency** **Model:** Celsius™ Catheter D-1145-XX-S (XX=05-06, 08, 28) Celsius™ Catheter D-1165-XX-S (XX=01-03, 22) Celsius™ Catheter D-1196-XX-S (XX=01-04, 11, 15) Celsius™ Catheter D-1198-XX-S (XX=01-06, 13-14) Celsius™ Catheter D-1200-XX-S (XX=01-06)	*Intended Purpose: The CELSIUS™ Catheter is intended for cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation*
Basic UDI (EZ Steer™ Bi-Directional): 08468350a0016F4 **Device Name:** EZ Steer™ Bi-Directional Catheter **Type: C020301 - Cardiac Tissue Ablation Electrocatheters, Radiofrequency** **Model:** EZ Steer™ Bi-Directional Catheter D-1270-XX-S (XX=01-05)	*Intended Purpose: The EZ STEER™ Bi-Directional Catheter is intended for cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation.* *.*
Basic UDI (Celsius RMT): 08468350a0017F6 **Device Name:** Celsius RMT Catheter **Type: C020301 - Cardiac Tissue Ablation Electrocatheters, Radiofrequency** **Model:**Celsius RMT Catheter D-1249-XX-S (XX=01)	*Intended Purpose: The CELSIUS™ RMT Catheter is intended for cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation*
Basic UDI (NaviStar): 08468350a0016F4 **Device Name:** NaviStar™ Catheter **Type: C020301 - Cardiac Tissue Ablation Electrocatheters, Radiofrequency** **Model:**	*Intended Purpose: The NAVISTAR™ Catheter is intended for cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation*

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NaviStar™ Catheter D-1183-XX-S (XX=05-08, 13, 20, 30, 32)	
Basic UDI (EZ Steer™ Nav Bi-Directional): 08468350a0016F4 **Device Name:** EZ Steer™ Nav Bi-Directional Catheter **Type: C020301 - Cardiac Tissue Ablation Electrocatheters, Radiofrequency** **Model:** EZ Steer™ Nav Bi-Directional Catheter D-1268-XX-S (XX=01-05)	*Intended Purpose: The EZ STEER™ NAV Bi-Directional Catheter is intended for cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation.*
Basic UDI (NaviStar RMT): 08468350a0017F6 **Device Name:** NaviStar RMT Catheter **Type: C020301 - Cardiac Tissue Ablation Electrocatheters, Radiofrequency** **Model:**NaviStar RMT Catheter D-1257-XX-S (XX=01)	*Intended Purpose: The NAVISTAR™ RMT Catheter is intended for cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation*

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Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	31-07-2023	3826381CN30	First issue

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