

Number: 3903009TD01

# 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.: To be specified

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.

B.T.M. Holtus  
Managing Director

J.A. van Vugt  
Principal Certification Manager

First Issued: 5.1.22

Date: 5.1.22

Expiry date: 1.1.23

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



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

<b>Class III</b> <b>C020301 - Cardiac Tissue Ablation Electrocatheters, Radiofrequency</b>	
<b>Basic UDI (THERMOCOOL SMARTTOUCH):</b> <b>08468350a0008F5</b>  THERMOCOOL SMARTTOUCH™ Uni-Directional Navigational Catheter D-1336-XX-S (XX = 01-03)  THERMOCOOL SMARTTOUCH™ Bi-Directional Navigation Catheter D-1327-XX-S (XX = 01-05)	<i>Intended Purpose: The THERMOCOOL SMARTTOUCH™ Uni-Directional and Bi-Directional Navigation Catheters provide a real time measurement of contact force between the catheter tip and heart wall, as well as location information when used with the CARTO™ 3 System.</i>
<b>Basic UDI (THERMOCOOL SMARTTOUCH SF):</b> <b>08468350a0010EQ</b>  THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigational Catheter D-1347-XX-S (XX = 01-03)  THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter D-1348-XX-S (XX = 01-05)	<i>Intended Purpose: The THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheters provide a real time measurement of contact force between the catheter tip and heart wall, as well as location information when used with the CARTO™ 3 System.</i>

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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.

Date of Issue certificate	Certification Notice Reference	Action
5-1-22	3826381CN15	First issue

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