

DECLARATION OF CONFORMITY

(Following the provisions of the Medical Devices Directive 93/42/EEC)

Manufacturer Name: Biosense Webster, Inc.

Manufacturer Address: 31 Technology Drive, Suite 200
Irvine, CA 92618

EU Representative Name: Biosense Webster (Europe)

EU Representative Address: Johnson & Johnson Medical NV/SA
Leonardo Da Vincilaan 15
1831 Diegem, Belgium

Design Site Name or Address: Biosense Webster, Inc.
15715 Arrow Highway
Irwindale, CA 91706

Product Identification

| Product Name | European Part Number | Manufacturing Part Number |
|------------------------------------|----------------------|---------------------------|
| SmartAblate™ Irrigation Tubing Set | SAT001 | D-1320-01-S |

Product Classification: Class IIa. Rule 2, Annex IX, MDD 93/42/EEC


We, being the manufacturer, hereby declare that the Product(s) covered by this declaration conforms with the Essential Requirements, which apply to them (Annex I).

This declaration is supported by the following elements:

Technical File Number: TF 1017, SmartAblate™ Irrigation Tubing Set, June 14, 2011**Full Quality Assurance (Annex II):** No. CE 666431**Date of Issue of the Active Certificate:** May 04, 2021

The above certificate issued by the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 2797).

Approval:


Melissa C. Schultz
Associate Director, Regulatory Affairs
Biosense Webster, Inc07 JULY 2021

Date