

DECLARATION OF CONFORMITY

(Following the provisions of the Medical Devices Directive 93/42/EEC and the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment)

Manufacture Name:	Biosense Webster, Inc.
Manufacture 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 and Address:	Biosense Webster, Inc. 15715 Arrow Highway Irwindale, CA 91706

Product Identification

Product Name	European Part Number	Manufacturing Part Number
Deflectable Tip Electrophysiology Catheters	See Attached List	See Attached List

Directive 93/42/EEC Declaration (MDD):

Product Classification: Class III Annex IX, Rule 7 MDD 93/42/EEC

We, being the manufacturer, hereby declare that the Product(s) covered by this declaration conforms with the Medical Devices Directive 93/42/EEC Essential Requirements, which apply to them (Annex I).

This declaration is supported by the following elements:

Design Dossier Name & Number: Various

Design Examination Certificate: No. CE Number 666433

CE Certificate of Quality Assurance (Annex II): Certificate No., CE Number CE 666431

Both above certificates issued the British Standards Institution, a Notified Body under the Medical Device Directive 93/42/EEC (Notified Body Number 2797).

Directive 2011/65/EU declaration (RoHS):

We, being the manufacturer, declare that the products listed above meet the applicable provisions of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment including applicable harmonized standards listed in the above referenced Technical File.

This declaration of conformity with Directive 2011/65/EU declaration (RoHS) is issued under the sole responsibility of the manufacturer.

The product is in compliance with: EN 50581 - Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Approval:



Biosense Webster, Inc

07 JULY 2021

Date

BRAND NAME	EU CATALOG	PRODUCT/PART NUMBER
Celsius	35G17R	D-1145-05-S
Celsius	35G37R	D-1145-06-S
Celsius	35G47R	D-1145-07-S
Celsius	35G07R	D-1145-08-S
Celsius	SW1145028	D-1145-28-S
Celsius	35H07R	D-1146-07-S
Celsius	35H17R	D-1146-08-S
Celsius	35H37R	D-1146-09-S
Celsius	35J17R	D-1165-01-S
Celsius	35J37R	D-1165-02-S
Celsius	35J57R	D-1165-03-S
Celsius	35J47R	D-1165-04-S
Celsius	35J-60R	D-1165-22-S
Celsius	35K-17R	D-1166-01-S
Celsius	35K37R	D-1166-02-S
Celsius	35K-57R	D-1166-03-S
Celsius	35K-30R	D-1166-14-S
Celsius	35K-50R	D-1166-16-S
Celsius	35K-60R	D-1166-21-S
Celsius	34E-30Q	D-1216-10-S
Celsius	34E50Q	D-1216-12-S
Celsius	36N67R	D-1216-13-S
Celsius	36N-J7R	D-1216-15-S
Celsius	SW1216-017	D-1216-17-S
Celsius	34E-60R	D-1216-19-S
Celsius	34E-J0R	D-1216-21-S
Celsius	34D17R	D-1196-01-S
Celsius	34D37R	D-1196-02-S
Celsius	34D47R	D-1196-03-S
Celsius	34D57R	D-1196-04-S
Celsius	34D30Q	D-1196-11-S
Celsius	34D50Q	D-1196-13-S
Celsius	36DJ7R	D-1196-15-S
Celsius	SW1196017	D-1196-17-S
Celsius	34D-J0R	D-1196-21-S
Celsius	36N07R	D-1198-01-S
Celsius	36N17R	D-1198-02-S
Celsius	36N27R	D-1198-03-S

Celsius	36N37R	D-1198-04-S
Celsius	36N47R	D-1198-05-S
Celsius	36N57R	D-1198-06-S
Celsius	36N-16R	D-1198-08-S
Celsius	36N-26R	D-1198-09-S
Celsius	36N-36R	D-1198-10-S
Celsius	36N-56R	D-1198-12-S
Celsius	35A07R	D-1198-13-S
Celsius	35E37R	D-1198-14-S
Celsius	36O07R	D-1200-01-S
Celsius	36O17R	D-1200-02-S
Celsius	36O27R	D-1200-03-S
Celsius	36O37R	D-1200-04-S
Celsius	36O47R	D-1200-05-S
Celsius	36O57R	D-1200-06-S
Celsius	35B07R	D-1200-13-S
Celsius	34E17R	D-1216-01-S
Celsius	34E37R	D-1216-02-S
Celsius	34E47R	D-1216-03-S
Celsius	34E57R	D-1216-04-S
Celsius DS	35S37R	D-1194-20-S
Celsius DS	35S17R	D-1194-21-S
Celsius DS	35S57R	D-1194-22-S
Celsius DS	D7TCJ8L162RT	D-1194-23-S
Celsius FLTR	D135501	D-1355-01-S
Celsius FLTR	D135502	D-1355-02-S
Celsius FLTR	D135901	D-1359-01-S
Celsius RMT	CR7TCS4RT	D-1249-01-S
Celsius RMT ThermoCool	CR7TCSIRT	D-1302-01-S
Celsius ThermoCool	35Q13R	D-1189-01-S
Celsius ThermoCool	35Q33R	D-1189-02-S
Celsius ThermoCool	35Q53R	D-1189-03-S
Celsius ThermoCool	35Q73R	D-1189-04-S
CRISTACATH ELECTROPHYSIOLOGY CATHETER	36Y39R	D-1171-22-S
DECANAV ELECTROPHYSIOLOGY CATHETER	R7D282CT	D-1285-01-S
DECANAV ELECTROPHYSIOLOGY CATHETER	R7F282CT	D-1285-02-S
Electrophysiology Catheter: Deflectable Braided Tip	D1164101	D-1164-101-S
Electrophysiology Catheter: Deflectable Braided Tip	36I-57R	D-1164-103-S
Electrophysiology Catheter: Deflectable Braided Tip	SW1164-109	D-1164-109-S
Electrophysiology Catheter: Deflectable Braided Tip	SW1164-110	D-1164-110-S
Electrophysiology Catheter-Deflectable Tip	36C07R	D-1172-100-S
Electrophysiology Catheter-Deflectable Tip	36C17R	D-1172-101-S

Electrophysiology Catheter-Deflectable Tip	36C-27R	D-1172-102-S
Electrophysiology Catheter-Deflectable Tip	36C37R	D-1172-103-S
Electrophysiology Catheter-Deflectable Tip	36C-47R	D-1172-104-S
Electrophysiology Catheter-Deflectable Tip	36C-57R	D-1172-105-S
EZ Steer	35I33R	D-1270-01-S
EZ Steer	35I55R	D-1270-02-S
EZ Steer	35IJJR	D-1270-03-S
EZ Steer	35I5JR	D-1270-04-S
EZ Steer	35I35R	D-1270-05-S
EZ Steer	35W33R	D-1271-01-S
EZ Steer	35W55R	D-1271-02-S
EZ Steer	35WJJR	D-1271-03-S
EZ Steer	35W5JR	D-1271-04-S
EZ Steer	35W35R	D-1271-05-S
EZ Steer DS	35U33R	D-1267-01-S
EZ Steer DS	35U55R	D-1267-02-S
EZ Steer DS	35UJJR	D-1267-03-S
EZ Steer DS	35U5JR	D-1267-04-S
EZ Steer DS	35U35R	D-1267-05-S
EZ Steer NAV	34B33M	D-1268-01-S
EZ Steer NAV	35B55M	D-1268-02-S
EZ Steer NAV	34BJJM	D-1268-03-S
EZ Steer NAV	34B5JM	D-1268-04-S
EZ Steer NAV	34B35M	D-1268-05-S
EZ Steer NAV DS	34L33M	D-1260-01-S
EZ Steer NAV DS	35L55M	D-1260-02-S
EZ Steer NAV DS	34LJJM	D-1260-03-S
EZ Steer NAV DS	34L5JM	D-1260-04-S
EZ Steer NAV DS	34L35M	D-1260-05-S
EZ Steer ThermoCool	36Q33M	D-1294-01-S
EZ Steer ThermoCool	36Q55M	D-1294-02-S
EZ Steer ThermoCool	36QJJM	D-1294-03-S
EZ Steer ThermoCool	36Q5JM	D-1294-04-S
EZ Steer ThermoCool	36Q35M	D-1294-05-S
EZ Steer ThermoCool NAV	36H33M	D-1292-01-S
EZ Steer ThermoCool NAV	36H55M	D-1292-02-S
EZ Steer ThermoCool NAV	36HJJM	D-1292-03-S
EZ Steer ThermoCool NAV	36H5JM	D-1292-04-S
EZ Steer ThermoCool NAV	36H35M	D-1292-05-S
HALO XP ELECTROPHYSIOLOGY CATHETER	36J13R	D-1160-29-S
HALO XP ELECTROPHYSIOLOGY CATHETER	36J14R	D-1160-34-S
HALO XP ELECTROPHYSIOLOGY CATHETER	36J16R	D-1160-37-S

HALO XP ELECTROPHYSIOLOGY CATHETER	36J17R	D-1276-01-S
HALO XP WITH AUTO ID ELECTROPHYSIOLOGY CATHETER	36J13RCT	D-1160-43-S
ISMUS CATH ELECTROPHYSIOLOGY CATHETER	36Y35R	D-1277-01-S
ISMUS CATH ELECTROPHYSIOLOGY CATHETER	36Y32R	D-1171-27-S
ISMUS CATH WITH AUTO ID ELECTROPHYSIOLOGY CATHETER	36Y32RCT	D-1171-34-S
Lasso	35O26R	D-1220-38-S
Lasso	35O36R	D-1220-39-S
Lasso	35O16R	D-1220-40-S
Lasso	35O46R	D-1220-41-S
Lasso	35T46R	D-1220-57-S
Lasso	35T26R	D-1220-60-S
Lasso	35T36R	D-1220-61-S
Lasso	35T56R	D-1220-64-S
Lasso	SW1220-071	D-1220-71-S
Lasso	SW1220-072	D-1220-72-S
Lasso	35O36RCT	D-1220-79-S
Lasso	35O26RCT	D-1220-80-S
Lasso	D7L2020CT	D-1220-81-S
Lasso	D7L2015CT	D-1220-82-S
Lasso 2515	35T2515R	D-1237-01-S
Lasso 2515	35O2515R	D-1237-02-S
Lasso 2515	SW1237-003	D-1237-03-S
Lasso 2515 NAV	35U2515R	D-1290-01-S
Lasso 2515 NAV	35P2515R	D-1290-02-S
LASSO 2515 NAV eco	D134301	D-1343-01-S
LASSO 2515 NAV eco	D134302	D-1343-02-S
LASSO NAV	DLN1215CT	D-1312-01-S
LASSO NAV	DLN2215CT	D-1312-02-S
Lasso Nav	DLN1220CT	D-1312-03-S
Lasso Nav	DLN2220CT	D-1312-04-S
LASSO NAV	DLN1225CT	D-1312-05-S
LASSO NAV	DLN2225CT	D-1312-06-S
Lasso Nav	D134901	D-1349-01-S
LASSO NAV	D134902	D-1349-02-S
LASSO NAV	D134903	D-1349-03-S
LASSO NAV	D134904	D-1349-04-S
LASSO NAV	D134905	D-1349-05-S
LASSO NAV	D134906	D-1349-06-S
NaviStar	34A15M	D-1183-05-S
NaviStar	34A25M	D-1183-06-S
NaviStar	34A35M	D-1183-07-S
NaviStar	34A55M	D-1183-08-S

NaviStar	34A45M	D-1183-13-S
NaviStar	34AJ5M	D-1183-20-S
NaviStar	SW1183022	D-1183-22-S
NaviStar	SW1183-030	D-1183-30-S
NaviStar	SW1183-031	D-1183-31-S
NaviStar	SW1183-032	D-1183-32-S
NaviStar	SW1184-031	D-1184-31-S
NaviStar	SW1184-032	D-1184-32-S
NaviStar	SW1184-035	D-1184-35-S
NaviStar DS	34J17M	D-1201-15-S
NaviStar DS	34J27M	D-1201-16-S
NaviStar DS	34J37M	D-1201-17-S
NaviStar DS	34J57M	D-1201-19-S
NaviStar DS	34JJ7M	D-1201-20-S
NaviStar RMT	NR7TCS4Y	D-1257-01-S
NaviStar RMT ThermoCool	NR7TCSIY	D-1266-01-S
NaviStar ThermoCool	34H17M	D-1197-14-S
NaviStar ThermoCool	34H27M	D-1197-15-S
NaviStar ThermoCool	34H37M	D-1197-16-S
NaviStar ThermoCool	34H57M	D-1197-17-S
NaviStar ThermoCool	34HJ7M	D-1197-18-S
NogaStar	D120705S	D-1207-05
NogaStar	D120707S	D-1207-07
NogaStar	D120708S	D-1207-08
PARAHISIAN ELECTROPHYSIOLOGY CATHETER	36L00Q	D-1097-552-S
ThermoCool SF	BDI35DDRT	D-1314-01-S
ThermoCool SF	BDI35FFRT	D-1314-02-S
ThermoCool SF	BDI35JJRT	D-1314-03-S
ThermoCool SF	BDI35FJRT	D-1314-04-S
ThermoCool SF	BDI35DFRT	D-1314-05-S
ThermoCool SF	BDI35BBRT	D-1314-06-S
ThermoCool SF	BDI35BDRT	D-1314-07-S
ThermoCool SF	BDI35BFRT	D-1314-08-S
ThermoCool SF	BDI35DJRT	D-1314-09-S
ThermoCool SF	D131601	D-1316-01-S
ThermoCool SF	D131602	D-1316-02-S
ThermoCool SF	D131603	D-1316-03-S
ThermoCool SF	D131604	D-1316-04-S
ThermoCool SF NAV	BNI35DDCT	D-1313-01-S
ThermoCool SF NAV	BNI35FFCT	D-1313-02-S
ThermoCool SF NAV	BNI35JJCT	D-1313-03-S
ThermoCool SF NAV	BNI35FJCT	D-1313-04-S

ThermoCool SF NAV	BNI35DFCT	D-1313-05-S
ThermoCool SF NAV	BNI35BBCT	D-1313-06-S
ThermoCool SF NAV	BNI35BDCT	D-1313-07-S
ThermoCool SF NAV	BNI35BFCT	D-1313-08-S
ThermoCool SF NAV	BNI35DJCT	D-1313-09-S
ThermoCool SF NAV	D131501	D-1315-01-S
ThermoCool SF NAV	D131502	D-1315-02-S
ThermoCool SF NAV	D131503	D-1315-03-S
ThermoCool SF NAV	D131504	D-1315-04-S
ThermoCool SF NAV	BNI35DDH	D-1317-01-S
ThermoCool SF NAV	BNI35FFH	D-1317-02-S
ThermoCool SF NAV	BNI35JJH	D-1317-03-S
ThermoCool SF NAV	BNI35FJH	D-1317-04-S
ThermoCool SF NAV	BNI35DFH	D-1317-05-S
ThermoCool SF NAV	BNI35BBH	D-1317-06-S
ThermoCool SF NAV	BNI35BDH	D-1317-07-S
ThermoCool SF NAV	BNI35BFH	D-1317-08-S
ThermoCool SF NAV	BNI35DJH	D-1317-09-S
ThermoCool SF NAV	D131801	D-1318-01-S
ThermoCool SF NAV	D131802	D-1318-02-S
ThermoCool SF NAV	D131803	D-1318-03-S
ThermoCool SF NAV	D131804	D-1318-04-S
ThermoCool SmartTouch	D132701	D-1327-01-S
ThermoCool SmartTouch	D132702	D-1327-02-S
ThermoCool SmartTouch	D132703	D-1327-03-S
ThermoCool SmartTouch	D132704	D-1327-04-S
ThermoCool SmartTouch	D132705	D-1327-05-S
ThermoCool SmartTouch	D133601	D-1336-01-S
ThermoCool SmartTouch	D133602	D-1336-02-S
ThermoCool SmartTouch	D133603	D-1336-03-S
THERMOCOOL SMARTTOUCH SF	D134701	D-1347-01-S
THERMOCOOL SMARTTOUCH SF	D134702	D-1347-02-S
THERMOCOOL SMARTTOUCH SF	D134703	D-1347-03-S
THERMOCOOL SMARTTOUCH SF	D134801	D-1348-01-S
THERMOCOOL SMARTTOUCH SF	D134802	D-1348-02-S
THERMOCOOL SMARTTOUCH SF	D134803	D-1348-03-S
THERMOCOOL SMARTTOUCH SF	D134804	D-1348-04-S
THERMOCOOL SMARTTOUCH SF	D134805	D-1348-05-S
WEBSTER CS CATHETER WITH AUTO ID	D135303	D-1353-03-S
WEBSTER CS CATHETER WITH AUTO ID	D135304	D-1353-04-S
WEBSTER CS Catheter With Auto ID Technology	D135305	D-1353-05-S
WEBSTER CS CATHETER WITH EZ STEER	36D5JR	D-1263-04-S

WEBSTER CS CATHETER WITH EZ STEER	36D35R	D-1263-05-S
WEBSTER CS CATHETER WITH EZ STEER	36G5JMCT	D-1263-06-S
WEBSTER CS CATHETER WITH EZ STEER AND AUTO ID	36G35QCT	D-1263-07-S
WEBSTER DUO-DECAPOLAR ELECTROPHYSIOLOGY CATHETER	D728260RT	D-1171-35-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	D107875	D-1078-75-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	D107877	D-1078-77-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	D5SAL252RT	D-1078-305-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36A07R	D-1078-319-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36A07Q	D-1078-63-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	35Y13Q	D-1078-64-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	35Y33Q	D-1078-65-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	SW1078-090	D-1078-90-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	35X31Q	D-1079-212-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36S31Q	D-1079-213-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36S30Q	D-1079-214-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36E30Q	D-1079-215-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	35X33Q	D-1079-216-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36S38Q	D-1079-217-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	35X58Q	D-1079-228-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	35X53Q	D-1079-229-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	35X34Q	D-1079-230-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	35X38Q	D-1079-231-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36B38R	D-1079-236-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36B33R	D-1079-237-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36B35R	D-1079-238-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	SW1079251	D-1079-251-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	SW1079-254	D-1079-254-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	SW1079257	D-1079-257-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36U-07R	D-1079-302-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	SW1079-305	D-1079-305-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	SW1079-307	D-1079-307-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	SW1079-323	D-1079-323-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36P30H	D-1095-33-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36P31H	D-1095-43-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36F30Q	D-1097-550-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36G33Q	D-1097-551-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36F-32Q	D-1097-554-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36C38R	D-1097-568-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36C33R	D-1097-569-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36C35R	D-1097-570-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	36D30Q	D-1097-571-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	SW1097-602	D-1097-602-S

WEBSTER ELECTROPHYSIOLOGY CATHETER	107832RT	D-1078-308-S
WEBSTER ELECTROPHYSIOLOGY CATHETER	D6A10DRP10RT	D-1079-234-S
WEBSTER WITH AUTO ID ELECTROPHYSIOLOGY CATHETER	36G33QCT	D-1097-589-S
WEBSTER WITH AUTO ID ELECTROPHYSIOLOGY CATHETER	36C38RCT	D-1097-590-S
WEBSTER WITH AUTO ID ELECTROPHYSIOLOGY CATHETER	35X33QCT	D-1079-258-S
WEBSTER WITH AUTO ID ELECTROPHYSIOLOGY CATHETER	36B38RCT	D-1079-259-S
WEBSTER WITH AUTO ID ELECTROPHYSIOLOGY CATHETER	36B33RCT	D-1079-260-S
WEBSTER WITH AUTO ID ELECTROPHYSIOLOGY CATHETER	36S31QCT	D-1079-261-S
Celsius	D8BTCGL	D-1165-13-S
Celsius	D8BTGL	D-1166-09-S
Celsius DS	D7TCE8L162RT	D-1194-24-S