English

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU DECLARATION OF CONFORMITY

Manufacturer's Name	Biosense Webster, Inc.,
Manufacturer's Address	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Manufacturer's Single Registration Number (SRN)	US-MF-000014219
Authorized Representative's Name and Address	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Authorized Representative's Single Registration Number (SRN)	BE-AR-000012231
Notified Body Name	DEKRA Certification B.V.
Notified Body Identification Number	NB 0344
Technical Documentation Number	TD0015
Product and Trade Name(s)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Product Code(s)/Product Range and Description	See table below
Intended Purpose	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Classification	Class III (Annex VIII, Rule 7)
GMDN Code	61785
EMDN Code	C020301
Basic UDI-DI	08468350a0010EQ
RoHS	We Biosense Webster, Inc., hereby declare the above listed Medical Device(s) complies with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

English

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU DECLARATION OF CONFORMITY

	restriction of the use of certain hazardous substances in electrical and electronic equipment.

This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer

We, Biosense Webster, Inc., hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.

This declaration is made on the basis of:

EU Technical Documentation Assessment Certificate Number 3903009TD01, issued by the Notified Body stated above, in accordance with Annex IX, Chapter II of the Medical Device Regulation (EU) 2017/745.

EU Quality System Certificate Number 3903009CE01, issued by the Notified Body stated above, in accordance with Annex IX, Chapters I and III of Medical Device Regulation (EU) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature	[redacted]	**Date**	January 14, 2022
Name/Title	Diana Bordley Sr. Director of Regulatory Affairs		
Signature	[redacted]	**Date**	19 JAN 2022
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance **Manufacturer's Person Responsible for Regulatory Compliance**		

Note: The English DoC is considered the "EN Master DoC". The signatures with date in the "EN Master DoC" represent at the same time the validity for the translated DoCs.

Ελληνικά (Greek)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

Όνομα κατασκευαστή	Biosense Webster, Inc.,
Διεύθυνση κατασκευαστή	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Ενιαίος Αριθμός Καταχώρησης Κατασκευαστή (SRN)	US-MF-000014219
Όνομα και διεύθυνση Εξουσιοδοτημένου Αντιπροσώπου	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Ενιαίος αριθμός καταχώρησης Εξουσιοδοτημένου Αντιπροσώπου (SRN)	BE-AR-000012231
Όνομα Κοινοποιημένου Οργανισμού	DEKRA Certification B.V.
Αριθμός Ταυτοποίησης Κοινοποιημένου Οργανισμού	NB 0344
Αριθμός τεχνικού φακέλου	TD0015
Ονομασία(ες) προϊόντος και εμπορική(ές) επωνυμία(ες)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Κωδικός(οί) προϊόντος(ων)/Σειρά και περιγραφή προϊόντων	See table below
Προβλεπόμενη χρήση	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Ταξινόμηση	Κατηγορία III (Παράρτημα VIII, Κανόνας 7)
Κωδικός GMDN	61785
Κωδικός GMDN	C020301

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Ελληνικά (Greek)

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

Τιμή βασικού UDI-DI	08468350a0010EQ
RoHS	Εμείς, Biosense Webster, Inc., διά του παρόντος δηλώνουμε ότι το προαναφερόμενο ιατροτεχνολογικό προϊόν (ή προϊόντα) συμμορφώνεται(ονται) με την Οδηγία 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 για τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό.

Η παρούσα Δήλωση συμμόρφωσης ΕΕ εκδίδεται με την αποκλειστική ευθύνη του κατασκευαστή.

Εμείς, Biosense Webster, Inc., διά του παρόντος δηλώνουμε ότι το προαναφερόμενο ιατροτεχνολογικό προϊόν (ή προϊόντα) συμμορφώνεται(ονται) με τον Κανονισμό για τα Ιατροτεχνολογικά Προϊόντα (ΕΕ) 2017/745.

Η παρούσα δήλωση πραγματοποιείται με βάση τον:

Αριθμό Πιστοποιητικού Αξιολόγησης Τεχνικού Φακέλου ΕΕ 3903009TD01, που εκδόθηκε από τον Κοινοποιημένο Οργανισμό που δηλώνεται παραπάνω, σύμφωνα με το Παράρτημα IX, Κεφάλαιο II του Κανονισμού για τα Ιατροτεχνολογικά Προϊόντα (ΕΕ) 2017/745.

Αριθμό Πιστοποιητικού Συστήματος Ποιότητας ΕΕ 3903009CE01, που εκδόθηκε από τον Κοινοποιημένο Οργανισμό που δηλώνεται παραπάνω, σύμφωνα με το Παράρτημα IX, Κεφάλαια I και III του Κανονισμού

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Σημείωση: Το αγγλικό έγγραφο θεωρείται ως το "EN κύριο έγγραφο". Οι υπογραφές με ημερομηνία στο "EN κύριο έγγραφο" αντιπροσωπεύουν ταυτόχρονα την εγκυρότητα των μεταφρασμένων εγγράφων.

Türkçe (Turkish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU DECLARATION OF CONFORMITY

Üreticinin Adı	Biosense Webster, Inc.
Üreticinin Adresi	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Üreticinin Eşsiz Kayıt Numarası (SRN)	US-MF-000014219
Yetkili Temsilcinin Adı ve Adresi	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Yetkili Temsilcinin Eşsiz Kayıt Numarası (SRN)	BE-AR-000012231
Onaylanmış Kuruluşun Adı	DEKRA Certification B.V.
Onaylanmış Kuruluşun Kimlik Numarası	NB 0344
Teknik Belge Numarası	TD0015
Ürün ve Marka Ad(lar)ı	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Ürün Kodları/Ürün Çeşitliliği ve Açıklaması	See table below
Hedeflenen Amaç	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Sınıflandırma	Sınıf III (Ek VIII, Kural 7)
GMDN Kodu	61785
EMDN Kodu	C020301
Temel UDI-DI değeri	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Türkçe (Turkish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU DECLARATION OF CONFORMITY

RoHS	Biosense Webster, Inc., olarak yukarıda listelenen Tıbbi Cihaz(lar)ın, Avrupa Parlamentosu ve Konseyinin 8 Haziran 2011 tarihli, 2011/65/EU sayılı elektrikli ve elektronik ekipmanlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin Direktifine uygun olduğunu beyan ederiz.

İşbu AB Uygunluk Beyanı, yalnızca Üreticinin sorumluluğu kapsamında verilir.

Biosense Webster, Inc., olarak yukarıda listelenen Tıbbi Cihaz(lar)ın (AB) 2017/745 sayılı Tıbbi Cihaz Yönetmeliği ile uyumlu olduğunu beyan ederiz.

Bu beyan şu esaslara göre yapılmıştır:

(AB) 2017/745 sayılı Tıbbi Cihaz Yönetmeliğindeki Ek IX, Bölüm II'ye uygun olarak yukarıda belirtilen Onaylanmış Kuruluş tarafından verilen AB Teknik Belge Değerlendirmesi Belge Numarası 3903009TD01.

(AB) 2017/745 sayılı Tıbbi Cihaz Yönetmeliğindeki Ek IX, Bölüm I ve III'e uygun olarak yukarıda belirtilen Onaylanmış Kuruluş tarafından verilen AB Kalite Sistemi Belge Numarası 3903009CE01.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance **Manufacturer's Person Responsible for Regulatory Compliance**		

Not: İngilizce Belge, "İngilizce Ana Belge" olarak kabul edilir. "İngilizce Ana Belge" içinde yer alan imzalar ve tarihler, aynı zamanda çevirisi yapılmış Belgelerin de geçerliliğini temsil eder.

Svenska (Swedish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-försäkran om överensstämmelse

Tillverkarens namn	Biosense Webster, Inc.,
Tillverkarens adress	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Tillverkarens Eudamed-registreringsnummer (SRN)	US-MF-000014219
Auktoriserad representants namn och adress	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Auktoriserad representants Eudamed-registreringsnummer (SRN)	BE-AR-000012231
Anmälda organets namn	DEKRA Certification B.V.
Anmälda organets id-nummer	NB 0344
Tekniskt dokumentationsnummer	TD0015
Produktnamn och handelsnamn	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Produktkod(er)/Produktsortiment och beskrivning	See table below
Avsett ändamål	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klassificering	Klass III (bilaga VIII, regel 7)
GMDN-kod	61785
EMDN-kod	C020301
Grundläggande UDI-DI-värde	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Svenska (Swedish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-försäkran om överensstämmelse

RoHS	Vi Biosense Webster, Inc., intygar härmed att ovan nämnda medicintekniska enhet(er) efterlever kraven i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användningen av vissa farliga ämnen i elektriska och elektroniska produkter.

Denna EU-försäkran om överensstämmelse ges ut på tillverkarens ansvar.

Vi, Biosense Webster, Inc., intygar härmed att ovan nämnda medicintekniska produkter efterlever kraven i EU-förordningen om medicintekniska produkter 2017/745.

Denna försäkran görs baserat på:

EU:s tekniska dokumentutvärdering, certifikatnummer 3903009TD01, utfärdat av anmält organ angivet ovan, i enlighet med bilaga IX, kapitel II i EU-förordningen om medicintekniska produkter 2017/745.

EU:s kvalitetssystem, certifikatnummer 3903009CE01, utfärdat av anmält organ angivet ovan, i enlighet med bilaga IX, kapitel I och III i EU-förordningen om medicintekniska produkter 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance **Manufacturer's Person Responsible for Regulatory Compliance**		

Obs: Den engelska EU-försäkran om överensstämmelse betraktas som originaldokument (EN Master DoC). Namnteckningarna i originaldokumentet representerar samtidigt giltighet för de översatta EU-försäkringarna om överensstämmelse.

Suomi (Finnish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

Valmistajan nimi	Biosense Webster, Inc.,
Valmistajan osoite	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Valmistajan yksilöllinen rekisteröintitunnus (SRN)	US-MF-000014219
Valtuutetun edustajan nimi ja osoite	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Valtuutetun edustajan yksilöllinen rekisteröintitunnus (SRN)	BE-AR-000012231
Ilmoitetun laitoksen nimi	DEKRA Certification B.V.
Ilmoitetun laitoksen tunnistenumero	NB 0344
Teknisen asiakirjan numero	TD0015
Tuote- ja kauppanimi (tai -nimet)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Tuotekoodi(t) / tuotetyyppi ja -kuvaus	

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Käyttötarkoitus	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Luokitus	Luokka III (liite VIII, sääntö 7)
GMDN-koodi	61785
EMDN-koodi	C020301
Basic UDI-DI -arvo	08468350a0010EQ

Suomi (Finnish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

RoHS	Me Biosense Webster, Inc., täten vakuutamme, että edellä mainittu lääkinnällinen laite (laitteet) on Euroopan parlamentin ja neuvoston direktiivin 2011/65/EU (annettu 8. kesäkuuta 2011) mukainen, koskien tiettyjen vaarallisten aineiden käytön rajoittamista sähkö- ja elektroniikkalaitteissa.

Tämä EU-vaatimustenmukaisuusvakuutus annetaan valmistajan yksinomaisella vastuulla.

Me Biosense Webster, Inc., vakuutamme, Inc., että edellä mainittu lääkinnällinen laite (laitteet) on lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 mukainen.

Tämä ilmoitus perustuu

EU:n teknisten asiakirjojen arviointitodistuksen numeroon 3903009TD01, jonka on myöntänyt yllä ilmoitettu laitos lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 liitteen IX luvun II mukaisesti.

EU:n laadunhallintajärjestelmän sertifikaattinumeroon 3903009CE01, jonka on myöntänyt yllä ilmoitettu laitos lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 liitteen IX lukujen I ja III mukaisesti.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance **Manufacturer's Person Responsible for Regulatory Compliance**		

Huomaa: Englanninkielinen vaatimustenmukaisuusvakuutus (DoC) vastaa asiakirjaa "EN Master DoC". Allekirjoitukset ja päiväykset "EN Master Doc" -asiakirjassa edustavat samalla käännettyjen vaatimustenmukaisuusvakuutusten voimassaoloa.

Slovenščina (Slovenian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

IZJAVA EU O SKLADNOSTI

Ime proizvajalca	Biosense Webster, Inc.,
Naslov proizvajalca	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Enotna registrska številka proizvajalca (SRN)	US-MF-000014219
Ime in naslov pooblaščenega predstavnika	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Enotna registrska številka pooblaščenega predstavnika (SRN)	BE-AR-000012231
Ime priglašenega organa	DEKRA Certification B.V.
Identifikacijska številka priglašenega organa	NB 0344
Številka tehnične dokumentacije	TD0015
Ime(-na) izdelka in trgovsko(-a) ime(-na)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Šifra(-e) izdelka / nabor izdelkov in opis	See table below
Predvideni namen	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Razvrščanje	Razred III (dodatek VIII, pravilo 7)
Šifra GMDN	61785
Šifra EMDN	C020301
Osnovna vrednost UDI-DI	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Slovenščina (Slovenian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

IZJAVA EU O SKLADNOSTI

RoHS	Biosense Webster, Inc., izjavljamo, da zgoraj navedeni medicinski pripomočki ustrezajo Direktivi 2011/65/EU Evropskega parlamenta in Sveta z dne 8. junija 2011 o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi.

Ta izjava EU o skladnosti je izdana na lastno odgovornost proizvajalca.

Biosense Webster, Inc., izjavljamo, da so zgoraj navedeni medicinski pripomočki v skladu z Uredbo o medicinskih pripomočkih (EU) 2017/745.

Ta izjava je dana na podlagi:

Certifikata EU o oceni tehnične dokumentacije št. 3903009TD01, ki ga je izdal zgoraj navedeni priglašeni organ v skladu z Dodatkom IX, Poglavjem II Uredbe o medicinskih pripomočkih (EU) 2017/745.

Certifikata EU o sistemu vodenja kakovosti št. 3903009CE01, ki ga je izdal zgoraj navedeni priglašeni organ v skladu z Dodatkom IX, Poglavjema I in III Uredbe o medicinskih pripomočkih (EU) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Opomba: Angleška različica izjave o skladnosti je »EN Master DoC«. Podpisi z datumom v dokumentu »EN Master DoC« hkrati veljajo tudi za prevedene izjave o skladnosti.

Slovensky (Slovak)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EÚ VYHLÁSENIE O ZHODE

Názov výrobcu	Biosense Webster, Inc.,
Adresa výrobcu	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Jediné registračné číslovýrobcu (SRN)	US-MF-000014219
Názov a adresa splnomocneného zástupcu	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Jedinné registračné číslo splnomocneného zástupcu (SRN)	BE-AR-000012231
Názov notifikovanej osoby	DEKRA Certification B.V.
Identifikačné číslo notifikovanej osoby	NB 0344
Číslo technickej dokumentácie	TD0015
Názov(-vy) a obchodný(-é) názov(-vy) výrobku	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Kódy výrobkov/radvýrobkov a opis výrobkov	See table below

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Účel určenia	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klasifikácia	Trieda III (dodatok VIII, pravidlo 7)
Kód GMDN	61785
Kód EMDN	C020301
Hodnota základného UDI-DI	08468350a0010EQ

Slovensky (Slovak)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EÚ VYHLÁSENIE O ZHODE

RoHS	My, Biosense Webster, Inc., týmto vyhlasujeme, že zdravotnícke pomôcky uvedené vyššie spĺňajú podmienky smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach.

Toto EÚ vyhlásenie o zhode sa vydáva na výhradnú zodpovednosť výrobcu.

My, Biosense Webster, Inc., týmto vyhlasujeme, že zdravotnícke pomôcky uvedené vyššie spĺňajú podmienky nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.

Toto vyhlásenie je uskutočnené na základe nasledovného:

Číslo certifikátu posúdenia technickej dokumentácie EÚ 3903009TD01, vydané notifikovaným orgánom uvedeným vyššie v súlade s kapitolou II dodatku IX nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.

Číslo certifikátu systému kvality EÚ 3903009CE01, vydané notifikovanou osobou uvedenou vyššie v súlade s kapitolami I a III dodatku IX nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance **Manufacturer's Person Responsible for Regulatory Compliance**		

Poznámka: Vyhlásenie o zhode v angličtine sa považuje za „Hlavné vyhlásenie o zhode v EN". Podpisy s dátumom v „Hlavnom vyhlásení o zhode v EN" v rovnakom čase zabezpečujú platnosť preložených vyhlásení o zhode.

Română (Romanian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARAȚIE DE CONFORMITATE UE

Denumire producător	Biosense Webster, Inc.,
Adresă producător	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Număr unic de înregistrare (SRN) producător	US-MF-000014219
Denumire și adresă reprezentant autorizat	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Număr unic de înregistrare (SRN) reprezentant autorizat	BE-AR-000012231
Denumire organism notificat	DEKRA Certification B.V.
Număr de identificare organism notificat	NB 0344
Număr documentație tehnică	TD0015
Denumire produs și denumire(i) comercială(e)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Cod(uri) produs/Gamă și descriere produs	See table below
Scop propus	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Clasificare	Clasă III (Anexă VIII, Regulă 7)
Cod GMDN	61785
Cod EMDN	C020301
Valoarea UDI-DI de bază	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Română (Romanian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARAȚIE DE CONFORMITATE UE

RoHS	Noi Biosense Webster, Inc., declarăm prin prezenta că dispozitivul/dispozitivele medical(e) de mai sus respectă Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice.

Prezenta Declarație de conformitate UE este emisă pe răspunderea exclusivă a producătorului.

Noi, Biosense Webster, Inc., declarăm prin prezenta că dispozitivul/dispozitivele medical(e) de mai sus respectă Regulamentul (UE) 2017/745 privind dispozitivele medicale.
Prezenta declarație se întocmește în baza:

Certificatului de evaluare a documentației tehnice UE cu numărul 3903009TD01, emis de organismul notificat de mai sus, în conformitate cu Anexa IX, Capitolul II din Regulamentul (UE) 2017/745 privind dispozitivele medicale.

Certificatului privind sistemul de calitate UE cu numărul 3903009CE01, emis de organismul notificat de mai sus, în conformitate cu Anexa IX, Capitolele I și III din Regulamentul (UE) 2017/745 privind dispozitivele medicale.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance **Manufacturer's Person Responsible for Regulatory Compliance**		

Notă: Declarația de conformitate în limba engleză este considerată „Declarația de Conformitate EN Master". Semnăturile cu dată din „Declarația de Conformitate EN Master" reprezintă, în același timp, validitatea pentru Declarațiile de Conformitate traduse.

Portuguese

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARAÇÃO DE CONFORMIDADE DA UE

Nome do fabricante	Biosense Webster, Inc.,
Endereço do fabricante	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Número único de registo do fabricante (SRN)	US-MF-000014219
Nome e endereço do representante autorizado	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Número único de registodo representante autorizado (SRN)	BE-AR-000012231
Nome do Organismo Notificado	DEKRA Certification B.V.
Número de identificação do Organismo Notificado	NB 0344
Número da documentação técnica	TD0015
Nome(s) comercial(is) e do produto	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Código(s) do produto/gama e descrição do produto	See table below
Finalidade	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Classificação	Classe III (Anexo VIII, Regra 7)
Código GMDN	61785
Código EMDN	C020301
Valor UDI-DI básico	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Portuguese

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARAÇÃO DE CONFORMIDADE DA UE

RoHS	A Biosense Webster, Inc., declara pelo presente que o(s) Dispositivo(s) médico(s) acima mencionado(s) está(ão) em conformidade com a Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos.

Esta Declaração de Conformidade da UE é emitida sob a exclusiva responsabilidade do Fabricante.

A Biosense Webster, Inc., declara pelo presente que o(s) Dispositivo(s) médico(s) acima mencionado(s) está(ão) em conformidade com o Regulamento (UE) 2017/745 relativo aos dispositivos médicos.

Esta declaração é elaborada com base no:

Número de certificado de avaliação da documentação técnica da UE 3903009TD01, emitido pelo Organismo Notificado acima mencionado, em conformidade com o capítulo II do anexo IX do Regulamento (UE) 2017/745 relativo aos dispositivos médicos.

Número de certificado do sistema de qualidade da UE 3903009CE01, emitido pelo Organismo Notificado acima mencionado, em conformidade com os capítulos I e III do anexo IX do Regulamento (UE) 2017/745 relativo aos dispositivos médicos.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Nota: a DC em inglês é considerada a "EN Master DoC". A assinatura datada na "EN Master DoC" representa ao mesmo tempo a validade para as DC traduzidas.

Polski (Polish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DEKLARACJA ZGODNOŚCI UE

Nazwa producenta	Biosense Webster, Inc.,
Adres producenta	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Niepowtarzalny numer rejestracyjny producenta (SRN)	US-MF-000014219
Nazwa i adres upoważnionego przedstawiciela	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela (SRN)	BE-AR-000012231
Nazwa jednostki notyfikowanej	DEKRA Certification B.V.
Numer identyfikacyjny jednostki notyfikowanej	NB 0344
Numer dokumentacji technicznej	TD0015
Nazwa(-y) produktu i nazwa(-y) handlowa(-e)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Kod(y) produktu/zakres i opis produktu	See table below
Przewidziane zastosowanie	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klasyfikacja	Klasa III (Aneks VIII, Zasada 7)
Kod GMDN	61785
Kod EMDN	C020301

European Part Number	**Manufacturing Part Number**	**Product description**
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Polski (Polish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DEKLARACJA ZGODNOŚCI UE

Wartość kodu Basic UDI-DI	08468350a0010EQ
RoHS	My, Biosense Webster, Inc., niniejszym oświadczamy, że wyżej wymieniony wyrób medyczny (wyroby medyczne) jest zgodny z Dyrektywą Parlamentu Europejskiego i Rady 2011/65/UE z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym.

Niniejsza Deklaracja Zgodności UE zostaje wydana na wyłączną odpowiedzialność producenta.

My, Biosense Webster, Inc., niniejszym oświadczamy, że wyżej wymieniony wyrób medyczny (wyroby medyczne) jest zgodny z rozporządzeniem w sprawie wyrobów medycznych (UE) 2017/745.

Oświadczenie to zostało złożone na podstawie:

Numer certyfikatu oceny dokumentacji technicznej UE 3903009TD01 wydanego przez wyżej wymienioną jednostkę notyfikowaną, zgodnie z załącznikiem IX, rozdziałem II rozporządzenia w sprawie wyrobów medycznych (UE) 2017/745.

Numer certyfikatu systemu jakości UE 3903009CE01 wydanego przez wyżej wymienioną jednostkę notyfikowaną, zgodnie z załącznikiem IX, rozdziałami I i III rozporządzenia w sprawie wyrobów medycznych (UE) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Uwaga: Dokument w języku angielskim jest uznawany jako „EN Master DoC" (Główny dokument w j. angielskim). Opatrzone datą podpisy zawarte w „EN Master DoC" pozostają równocześnie ważne dla przetłumaczonych dokumentów.

Norsk (Norwegian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-SAMSVARSERKLÆRING

Produsentens navn	Biosense Webster, Inc.,
Produsentens adresse	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Produsentens enkle registreringsnummer (SRN)	US-MF-000014219
Autorisert representants navn og adresse	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Autorisert representants enkle registreringsnummer (SRN)	BE-AR-000012231
Navn på kontrollorgan	DEKRA Certification B.V.
Identifikasjonsnummer for kontrollorgan	NB 0344
Teknisk dokumentasjonsnummer	TD0015
Produkt- og handelsnavn	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Produktkode(r)/produktsortiment og -beskrivelse	See table below
Tiltenkt formål	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klassifisering	Klasse III (vedlegg VIII, regel 7)
GMDN-kode	61785
EMDN-kode	C020301
Grunnleggende UDI-DI-verdi	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Norsk (Norwegian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-SAMSVARSERKLÆRING

RoHS	Vi, Biosense Webster, Inc., erklærer herved at de(n) ovennevnte medisinske enheten(e) er i samsvar med Europarlamentets og rådsdirektiv 2011/65/EU av 8. juni 2011 om begrensning i bruk av visse farlige stoffer i elektrisk og elektronisk utstyr.

Denne EU-samsvarserklæringen er utstedt på produsentens eget ansvar.

Vi, Biosense Webster, Inc., erklærer herved at de(n) ovennevnte medisinske enheten(e) er i samsvar med forordning (EU) 2017/745 om medisinsk utstyr.

Denne erklæringen er oppgitt på grunnlag av:

EU-sertifikatnummer for vurdering av teknisk dokumentasjon 3903009TD01, utstedt av kontrollorganet nevnt ovenfor, i samsvar med vedlegg IX, kapittel II i forordning (EU) 2017/745 om medisinsk utstyr.

EU-sertifikatnummer for kvalitetssystem 3903009CE01, utstedt av kontrollorganet nevnt ovenfor, i samsvar med vedlegg IX, kapittel I og III i forordning (EU) 2017/745 om medisinsk utstyr.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Merk: Det engelske dokumentet anses som det «engelske masterdokumentet». Signaturene med dato i det engelske masterdokumentet representerer også gyldighet av de oversatte dokumentene

.

Nederlands (Dutch)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-CONFORMITEITSVERKLARING

Naam fabrikant	Biosense Webster, Inc.,
Adres fabrikant	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Uniek registratienummer fabrikant (SRN)	US-MF-000014219
Naam en adres gemachtigde	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Uniek registratienummer fabrikant (SRN)	BE-AR-000012231
Naam aangemelde instantie	DEKRA Certification B.V.
Identificatienummer aangemelde instantie	NB 0344
Technisch documentatienummer	TD0015
Product- en handelsna(a)m(en)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Productcode(s)/productgroep en -beschrijving	See table below
Beoogd doeleind	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Classificatie	Klasse III (bijlage VIII, regel 7)
GMDN-code	61785
EMDN-code	C020301
Basic UDI-DI-waarde	08468350a0010EQ
RoHS	Wij Biosense Webster, Inc., verklaren hierbij dat hierboven vermeld medische hulpmiddel voldoet (hierboven vermelde

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Nederlands (Dutch)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-CONFORMITEITSVERKLARING

	medische hulpmiddelen voldoen) aan Richtlijn 2011/65/EU van het Europees Parlement en de Raad van 8 juni 2011 betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur.

De EU-conformiteitsverklaring wordt verstrekt onder de exclusieve verantwoordelijkheid van de fabrikant.

Wij, Biosense Webster, Inc., verklaren hierbij dat hierboven vermeld medische hulpmiddel voldoet/hierboven vermelde medische hulpmiddelen voldoen aan de verordening betreffende medische hulpmiddelen (EU) 2017/745.

Deze verklaring is opgesteld op basis van:

Certificaatnummer van de technische documentbeoordeling van de EU 3903009TD01, afgegeven door de hierboven vermelde aangemelde instantie, in overeenstemming met bijlage IX, hoofdstuk II van de verordening betreffende medische hulpmiddelen (EU) 2017/745.

Certificaatnummer van het EU-kwaliteitssysteem 3903009CE01, afgegeven door de hierboven vermelde aangemelde instantie, in overeenstemming met bijlage IX, hoofdstukken I en III van de verordening betreffende medische hulpmiddelen (EU) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Opmerking: De Engelse conformiteitsverklaring wordt beschouwd als de "Engelse standaard conformiteitsverklaring". De handtekeningen met datum in de "Engelse standaard conformiteitsverklaring" geven tegelijkertijd de geldigheid weer van de vertaalde conformiteitsverklaringen.

Magyar (Hungarian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-MEGFELELŐSÉGI NYILATKOZAT

Gyártó neve	Biosense Webster, Inc.,
Gyártó címe	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Gyártó egyedi regisztrációs száma (SRN)	US-MF-000014219
Meghatalmazott képviselő neve és címe	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	BE-AR-000012231
Bejelentett szervezet neve	DEKRA Certification B.V.
Bejelentett szervezet azonosítószáma	NB 0344
Műszaki dokumentáció száma	TD0015
Terméknév/terméknevek és kereskedelmi név/kereskedelmi nevek	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Termékkód(ok)/termékskála és -leírás	See table below
Rendeltetés	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Osztályozás	III. osztály (VIII. melléklet, 7. szabály)
GMDN-kód	61785
EMDN-kód	C020301
Alapvető UDI-DI értéke	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Magyar (Hungarian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-MEGFELELŐSÉGI NYILATKOZAT

RoHS	Mi, a(z) Biosense Webster, Inc., ezúton kijelentjük, hogy a fent említett orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és Tanács 2011. június 8-án kelt, az egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU irányelvének.

Ez az EU-megfelelőségi nyilatkozat a gyártó kizárólagos felelősségére kerül kiadásra.

Mi, a(z) Biosense Webster, Inc., ezúton kijelentjük, hogy a fent említett orvostechnikai eszköz(ök) megfelel(nek) az orvostechnikai eszközökről szóló (EU) 2017/745 rendeletnek.

A jelen nyilatkozat alapja:

A műszaki dokumentáció értékelésére vonatkozó EU-tanúsítvány száma: 3903009TD01, amelyet a fent megnevezett bejelentett szervezett adott ki az orvostechnikai eszközökről szóló (EU) 2017/745 rendelet IX. mellékletének II. fejezetével összhangban.

EU-minőségbiztosítási rendszer tanúsítványszáma: 3903009CE01, amelyet a fent megnevezett bejelentett szervezett adott ki az orvostechnikai eszközökről szóló (EU) 2017/745 rendelet IX. mellékletének I. És III. fejezetével összhangban.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Megjegyzés: Az „EN Master Doc" című dokumentum minősül az angol nyelvű Megfelelőségi Nyilatkozatnak. Az „EN Master Doc" dokumentumban szereplő dátum és aláírások egyidejűleg a lefordított Megfelelőségi Nyilatkozatokra is érvényesek

Latviešu (Latvian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ES ATBILSTĪBAS DEKLARĀCIJA

Ražotāja nosaukums	Biosense Webster, Inc.,
Ražotāja adrese	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Ražotāja vienotais reģistrācijas numurs (SRN)	US-MF-000014219
Pilnvarotā pārstāvja nosaukums un adrese	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Pilnvarotā pārstāvja vienotais reģistrācijas numurs (SRN)	BE-AR-000012231
Paziņotās struktūras nosaukums	DEKRA Certification B.V.
Paziņotās struktūras identifikācijas numurs	NB 0344
Tehniskās dokumentācijas numurs	TD0015
Izstrādājuma nosaukums un tirdzniecības nosaukums (-i)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Izstrādājuma kods(-i) / Izstrādājumu klāsts un apraksts	See table below
Paredzētais nolūks	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klasifikācija	Klase III (Pielikums VIII, Noteikums 7)
GMDN kods	61785
EMDN kods	C020301
Pamata UDI-DI vērtība	08468350a0010EQ

European Part Number	**Manufacturing Part Number**	**Product description**
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Latviešu (Latvian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ES ATBILSTĪBAS DEKLARĀCIJA

RoHS	Mēs, Biosense Webster, Inc., ar šo apliecinām, ka iepriekšminētā(-s) medicīniskā(-s) ierīce(-s) atbilst Eiropas Parlamenta un Padomes 2011. gada 8. jūnija Direktīvai 2011/65/ES par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās.

Par šīs ES atbilstības deklarācijas izdošanu pilnībā ir atbildīgs ražotājs.

Mēs, Biosense Webster, Inc., ar šo apliecinām, ka iepriekšminētā(-s) medicīniskā(-s) ierīce(-s) atbilst Medicīnisko ierīču regulai (ES) 2017/745.

Šīs deklarācijas sagatavošanas pamats ir:

ES Tehniskās dokumentācijas novērtējuma sertifikāts numur 3903009TD01, ko izdevusi iepriekšminētā paziņotā struktūra saskaņā ar Medicīnas ierīču regulas (ES) 2017/745 IX pielikuma II nodaļu.

ES kvalitātes sistēmas sertifikāts numur 3903009CE01, ko izdevusi iepriekšminētā paziņotā struktūra saskaņā ar Medicīnas ierīču regulas (ES) 2017/745 IX pielikuma I nodaļu un III nodaļu.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Piezīme. Atbilstības deklarācija angļu valodā uzskatāma par "EN atbilstības deklarācijas oriģinālu". Paraksti, norādot datumu "EN atbilstības deklarācijas oriģinālā", tajā pašā laikā reprezentē tulkoto atbilstības deklarāciju derīgumu.

Italian

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DICHIARAZIONE DI CONFORMITÀ UE

Nome del fabbricante	Biosense Webster, Inc.,
Indirizzo del fabbricante	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Numero di registrazione unico del fabbricante (SRN)	US-MF-000014219
Nome e indirizzo del mandatario	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Numero di registrazione unicodel mandatario (SRN)	BE-AR-000012231
Nome dell'organismo notificato	DEKRA Certification B.V.
Numero di identificazione dell'organismo notificato	NB 0344
Numero della documentazione tecnica	TD0015
Nomi dei prodotti e denominazioni commerciali	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Codici del prodotto/Gamma e descrizione del prodotto	See table below
Scopo previsto	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Classificazione	Classe III (Appendice VIII, Regola 7)
Codice GMDN	61785
Codice EMDN	C020301

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Italian

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DICHIARAZIONE DI CONFORMITÀ UE

Valore UDI-DI di base	08468350a0010EQ
RoHS	Noi di Biosense Webster, Inc., con la presente dichiariamo che i dispositivi medici sopra indicati sono conformi alla Direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche.

Questa Dichiarazione di conformità UE è rilasciata sotto l'esclusiva responsabilità del fabbricante.

Noi di Biosense Webster, Inc., con la presente dichiariamo che i dispositivi medici indicati sopra sono conformi al Regolamento sui dispositivi medici (UE) 2017/745.

Questa dichiarazione è effettuata sulla base di:

Numero del certificato della valutazione della documentazione tecnica UE 3903009TD01, rilasciato dall'organismo notificato indicato sopra, in conformità all'Appendice IX, Capitolo II del Regolamento sui dispositivi medici (UE) 2017/745.

Numero del certificato del sistema di qualità UE 3903009CE01, rilasciato dall'organismo notificato indicato sopra, in conformità all'Appendice IX, Capitoli I e III del Regolamento sui dispositivi medici (UE) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Nota: la Dichiarazione di conformità in inglese è la "Dichiarazione di conformità master in inglese". Le firme datate nella "Dichiarazione di conformità master in inglese" rendono valide anche le Dichiarazioni di conformità tradotte.

Hrvatski (Croatian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU IZJAVA O SUKLADNOSTI

Naziv proizvođača	Biosense Webster, Inc.,
Adresa proizvođača	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Jedinstveni registracijski broj proizvođača (SRN)	US-MF-000014219
Naziv i adresa ovlaštenog predstavnika	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Jedinstveni registracijski broj ovlaštenog predstavnika (SRN)	BE-AR-000012231
Naziv prijavljenog tijela	DEKRA Certification B.V.
Identifikacijski broj prijavljenog tijelai	NB 0344
Broj tehničke dokumentacije	TD0016
Nazivi proizvoda i trgovačka imena proizvoda	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Šifre proizvoda / asortiman proizvoda i opis	See table below
Namjena	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klasifikacija	Klasa III (Prilog VIII, pravilo 7)
GMDN šifra	61785
EMDN šifra	C020301
Vrijednost za osnovni UDI-ID	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Hrvatski (Croatian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU IZJAVA O SUKLADNOSTI

RoHS	Biosense Webster, Inc., izjavljuje da su gore navedeni medicinski proizvodi usklađeni s Direktivom 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi.

Ova EU izjava o sukladnosti izdana je pod isključivom odgovornošću proizvođača.

Biosense Webster, Inc., izjavljuje da su gore navedeni medicinski proizvodi usklađeni s Uredbom (EU) 2017/745 o medicinskim proizvodima.

Ova se izjava temelji na:

EU potvrdi o ocjenjivanju tehničke dokumentacije broj 3903009TD01, koju je izdalo gore navedeno prijavljeno tijelo u skladu s Prilogom IX. poglavljem II. Uredbe (EU) 2017/745 o medicinskim proizvodima.

EU potvrdi o sustavu upravljanja kvalitetom broj 3903009CE01, koju je izdalo gore navedeno prijavljeno tijelou skladu s Prilogom IX. poglavljima I. i III. Uredbe (EU) 2017/745 o medicinskim proizvodima.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Napomena: engleska Izjava o sukladnosti smatra se „Glavnom Izjavom o sukladnosti na engleskom jeziku". Potpisi i datum u „ Glavnoj Izjavi o sukladnosti na engleskom jeziku" istodobno potvrđuju valjanost prevedenih verzija Izjave u sukladnosti.

Français (French)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DÉCLARATION DE CONFORMITÉ UE

Nom du fabricant	Biosense Webster, Inc.,
Adresse du fabricant	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Numéro d'enregistrement unique du fabricant (SRN)	US-MF-000014219
Nom et adresse du mandataire	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Numéro d'enregistrement unique du mandataire (SRN)	BE-AR-000012231
Nom de l'organisme notifié	DEKRA Certification B.V.
Numéro d'identification de l'organisme notifié	NB 0344
Numéro de documentation technique	TD0015
Nom(s) et dénomination(s) commerciale(s) du produit	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Code(s) du produit/Gamme et description du produit	See table below
Destination	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Classification	Classe III (Annexe VIII, règle 7)
Code GMDN	61785
Code EMDN	C020301
Valeur de l'IUD-ID de base	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Français (French)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DÉCLARATION DE CONFORMITÉ UE

RoHS	Nous, Biosense Webster, Inc., déclarons par les présentes que le ou les dispositifs médicaux énumérés ci-dessus sont conformes à la directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques.

Cette déclaration de conformité UE est délivrée sous la responsabilité exclusive du fabricant.

Nous, Biosense Webster, Inc., déclarons par les présentes que le ou les dispositifs médicaux énumérés ci-dessus sont conformes au règlement (UE) 2017/745 relatif aux dispositifs médicaux.

Cette déclaration est faite sur la base du :

Numéro de certificat UE relatif à l'évaluation de la documentation technique 3903009TD01, délivré par l'organisme notifié susmentionné, conformément à l'Annexe IX, chapitre II du règlement (UE) 2017/745 relatif aux dispositifs médicaux.

Numéro de certificat UE relatif au système qualité 3903009CE01, délivré par l'organisme notifié susmentionné, conformément à l'Annexe IX, chapitres I et III du règlement (UE) 2017/745 relatif aux dispositifs médicaux.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Remarque : la déclaration de conformité en anglais est considérée comme la « déclaration de conformité EN principale ». Les signatures datées dans la « déclaration de conformité EN principale » attestent également de la validité des déclarations de conformité traduites.

Español (Spanish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARACIÓN DE CONFORMIDAD DE LA UE

Nombre del fabricante	Biosense Webster, Inc.,
Dirección del fabricante	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Número de registro único del fabricante (SRN)	US-MF-000014219
Nombre y dirección del representante autorizado	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Número de registro único del representante autorizado (SRN)	BE-AR-000012231
Nombre del organismo notificado	DEKRA Certification B.V.
Número de identificación del organismo notificado	NB 0344
Número de documentación técnica	TD0015
Denominaciones y nombres comerciales del producto	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Código del producto/gama y descripción del producto	See table below
Finalidad prevista	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Clasificación	Clase III (anexo VIII, regla 7)
Código GMDN	61785
Código EMDN	C020301
Valor de UDI-DI básico	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Español (Spanish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARACIÓN DE CONFORMIDAD DE LA UE

RoHS	Nosotros, Biosense Webster, Inc., por la presente declaramos que los productos sanitarios indicados anteriormente cumplen la Directiva 2011/65/UE del Parlamento Europeo y del Consejo, de 8 de junio de 2011, sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos.

Esta Declaración de conformidad de la UE se emite bajo la responsabilidad exclusiva del fabricante.

Nosotros, Biosense Webster, Inc., por la presente declaramos que los productos sanitarios indicados anteriormente cumplen el Reglamento sobre productos sanitarios (UE) 2017/745.

Esta declaración se realiza basándose en:

Número de certificado de la evaluación de documentación técnica de la UE, 3903009TD01, emitido por el organismo notificado indicado anteriormente, de conformidad con el anexo IX, capítulo II del Reglamento sobre productos sanitarios (UE) 2017/745.

Número de certificado del sistema de calidad de la UE, 3903009CE01, emitido por el organismo notificado indicado anteriormente, de conformidad con el anexo IX, capítulos I y III del Reglamento sobre productos sanitarios (UE) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Nota: La DoC (declaración de conformidad) en inglés se considera la "DoC maestra en inglés". Las firmas con fecha en la "DoC maestra en inglés" representan al mismo tiempo la validez de las DoC traducidas.

Eesti keel (Estonian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ELi VASTAVUSDEKLARATSIOON

Tootja nimi	Biosense Webster, Inc.,
Tootja aadress	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Tootja unikaalne registreerimisnumber (SRN)	US-MF-000014219
Volitatud esindaja nimi ja aadress	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Volitatud esindaja unikaalne registreerimisnumber (SRN)	BE-AR-000012231
Teavitatud asutuse nimi	DEKRA Certification B.V.
Teavitatud asutuse identifitseerimisnumber	NB 0344
Tehnilise dokumentatsiooni number	TD0015
Toote nimetus(ed) ja kaubanimi (-nimed)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Tootekood(id) / tooteseeria ja kirjeldus	See table below
Sihtotstarve	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Liigitamine	Klass III (lisa VIII, reegel 7)
GMDN-kood	61785
EMDN-kood	C020301
Põhi-UDI-DI väärtus	08468350a0010EQ

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Eesti keel (Estonian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ELi VASTAVUSDEKLARATSIOON

RoHS	Meie, Biosense Webster, Inc., deklareerime käesolevaga, et ülalloetletud meditsiiniseade (-seadmed) vastab (vastavad) Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivile 2011/65/EÜ teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes.

See ELi vastavusdeklaratsioon on välja antud üksnes tootja vastutusel.

Meie, Biosense Webster, Inc., deklareerime käesolevaga, et ülalloetletud meditsiiniseade (-seadmed) vastab (vastavad) meditsiiniseadmete määrusele (EL) 2017/745.

See deklaratsioon põhineb järgmisel:

ELi tehnilise dokumentatsiooni hindamise sertifikaat nr 3903009TD01, mille on välja andnud ülalnimetatud teavitatud asutus kooskõlas meditsiiniseadmete määruse (EL) 2017/745 IX lisa II peatükiga;

ELi kvaliteedisüsteemi sertifikaat nr 3903009CE01, mille on välja andnud ülalnimetatud teavitatud asutus kooskõlas meditsiiniseadmete määruse (EL) 2017/745 IX lisa I ja III peatükiga.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance **Manufacturer's Person Responsible for Regulatory Compliance**		

Märkus: ingliskeelset vastavusdeklaratsiooni loetakse ingliskeelseks originaalvastavusdeklaratsiooniks. Kuupäevaga allkirjad ingliskeelses originaalvastavusdeklaratsioonis tähistavad ühtlasi tõlgitud vastavusdeklaratsioonide kehtivust.

Deutsch (German)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-KONFORMITÄTSERKLÄRUNG

Name des Herstellers	Biosense Webster, Inc.,
Adresse des Herstellers	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Einmalige Registrierungsnummer des Herstellers (SRN)	US-MF-000014219
Name und Adresse des bevollmächtigten Vertreters	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Einmalige Registrierungsnummer des bevollmächtigten Vertreters (SRN)	BE-AR-000012231
Name der Benannten Stelle	DEKRA Certification B.V.
Identifikationsnummer der Benannten Stelle	NB 0344
Nummer der technischen Dokumentation	TD0015
Produkt- und Handelsname	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Produktcode(s)/Produktpalette und Beschreibung	See table below
Zweckbestimmung	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klassifizierung	Klasse III (Anhang VIII, Regel 7)
GMDN-Code	61785
EMDN-Code	C020301

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Deutsch (German)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-KONFORMITÄTSERKLÄRUNG

Basis-UDI-DI-Wert	08468350a0010EQ
RoHS	Wir Biosense Webster, Inc., erklären hiermit, dass das bzw. die oben aufgeführte(n) Medizinprodukt(e) die Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten erfüllt bzw. erfüllen.

Diese EU-Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.

Wir, Biosense Webster, Inc., erklären hiermit, dass das bzw. die oben aufgeführte(n) Medizinprodukt(e) die Verordnung (EU) 2017/745 über Medizinprodukte erfüllt bzw. erfüllen.

Diese Erklärung wird auf folgender Grundlage ausgestellt:

EU-Zertifikatsnummer zur Bewertung technischer Dokumentationen 3903009TD01, ausgestellt von der oben genannten Benannten Stelle, in Übereinstimmung mit Anhang IX, Kapitel II der Verordnung (EU) 2017/745 über Medizinprodukte.

EU-Zertifikatsnummer für Qualitätssicherungssysteme 3903009CE01, ausgestellt von der oben genannten Benannten Stelle, in Übereinstimmung mit Anhang IX, Kapitel I und III der Verordnung (EU) 2017/745 über Medizinprodukte.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Hinweis: Das englische Dokument ist als „englisches Masterdokument" anzusehen. Die datierten Unterschriften im „englischen Masterdokument" begründen gleichzeitig die Gültigkeit der übersetzten Dokumente.

Dansk (Danish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-OVERENSSTEMMELSESERKLÆRING

Fabrikantens navn	Biosense Webster, Inc.,
Fabrikantens adresse	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Fabrikantens individuelle registreringsnummer (SRN)	US-MF-000014219
Autoriseret repræsentants navn og adresse	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Autoriseret repræsentants individuelle registreringsnummer (SRN)	BE-AR-000012231
Navn på det bemyndigede organ	DEKRA Certification B.V.
Bemyndiget organs identifikationsnummer	NB 0344
Teknisk dokumentationsnummer	TD0015
Produkt- og handelsnavn(e)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Produktkode(r)/produktsortiment og -beskrivelse	See table below
Erklæret formål	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klassificering	Klasse III (Bilag VIII, Regel 7)
GMDN-kode	61785
EMDN-kode	C020301

European Part Number	**Manufacturing Part Number**	**Product description**
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Dansk (Danish)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU-OVERENSSTEMMELSESERKLÆRING

Fælles specifikationer	08468350a0010EQ
RoHS	Undertegnede, Biosense Webster, Inc., erklærer herved, at ovennævnte medicinske udstyr opfylder kravene i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr.

Denne EU-overensstemmelseserklæring udstedes på fabrikantens eneansvar.

Undertegnede, Biosense Webster, Inc., erklærer herved, at ovennævnte medicinske udstyr opfylder kravene i forordning (EU) 2017/745 om medicinsk udstyr.

Denne erklæring afgives på grundlag af:

EU-teknisk dokumentation Vurderingsattestnummer 3903009TD01, udstedt af det bemyndigede organ, der er anført ovenfor, i overensstemmelse med bilag IX, kapitel II i forordning (EU) 2017/745 om medicinsk udstyr.

EU-kvalitetssystem Certifikatnummer 3903009CE01, udstedt af det bemyndigede organ, der er anført ovenfor, i overensstemmelse med bilag IX, kapitel I og III forordning (EU) 2017/745 om medicinsk udstyr.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Bemærk: Den engelske overensstemmelseserklæring betragtes som den engelske masteroverensstemmelseserklæring ("EN Master DoC"). De daterede underskrifter i "EN Master DoC" repræsenterer samtidig gyldigheden af de oversatte overensstemmelseserklæringer.

Česky (Czech)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU PROHLÁŠENÍ O SHODĚ

Název výrobce	Biosense Webster, Inc.,
Adresa výrobce	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Jediné registrační číslo výrobce (SRN)	US-MF-000014219
Název a adresa zplnomocněného zástupce	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Jediné registrační číslo zplnomocněného zástupce (SRN)	BE-AR-000012231
Název oznámeného subjektu	DEKRA Certification B.V.
Identifikační číslo oznámeného subjektu	NB 0344
Číslo technické dokumentace	TD0015
Název (názvy) a obchodní název (názvy) výrobku	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Kód(y) výrobku/výrobků / řada a popis výrobku/výrobků	<table><tr><th>European Part Number</th><th>Manufacturing Part Number</th><th>Product description</th></tr><tr><td>D134701</td><td>D-1347-01-S</td><td rowspan="3">THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter</td></tr><tr><td>D134702</td><td>D-1347-02-S</td></tr><tr><td>D134703</td><td>D-1347-03-S</td></tr><tr><td>D134801</td><td>D-1348-01-S</td><td rowspan="5">THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter</td></tr><tr><td>D134802</td><td>D-1348-02-S</td></tr><tr><td>D134803</td><td>D-1348-03-S</td></tr><tr><td>D134804</td><td>D-1348-04-S</td></tr><tr><td>D134805</td><td>D-1348-05-S</td></tr></table>
Určený účel	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klasifikace	Třída III (příloha VIII, pravidlo 7)
Kód GMDN	61785
Kód EMDN	C020301
Hodnota základního identifikátoru UDI-DI	08468350a0010EQ

Česky (Czech)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

EU PROHLÁŠENÍ O SHODĚ

RoHS	My, Biosense Webster, Inc., tímto prohlašujeme, že výše uvedený zdravotnický prostředek splňuje (uvedené zdravotnické prostředky splňují) požadavky směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních.

Toto prohlášení o shodě EU se vydává na výhradní odpovědnost výrobce.

My, Biosense Webster, Inc., tímto prohlašujeme, že výše uvedený zdravotnický prostředek splňuje (uvedené zdravotnické prostředky splňují) požadavky nařízení o zdravotnických prostředcích (EU) 2017/745.

Toto prohlášení vychází z:

certifikátu posouzení technické dokumentace EU číslo 3903009TD01, vydaného výše uvedeným oznámeným subjektem v souladu s kapitolou II přílohy IX nařízení o zdravotnických prostředcích (EU) 2017/745.

certifikátu systému kvality EU číslo 3903009CE01, vydaného výše uvedeným oznámeným subjektem v souladu s kapitolami I a III přílohy IX nařízení o zdravotnických prostředcích (EU) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Poznámka: Dokument v angličtině se považuje za „hlavní dokument v angličtině". Podpisy v „hlavním dokumentu v angličtině" zároveň reprezentují platnost přeložených dokumentů.

Български (Bulgarian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ДЕКЛАРАЦИЯ НА ЕС ЗА СЪОТВЕТСТВИЕ

Наименование на производителя	Biosense Webster, Inc.,
Адрес на производителя	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Производител - Единен регистрационен номер (SRN)	US-MF-000014219
Наименование и адрес на упълномощения представител	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Упълномощен представител - Единен регистрационен номер (SRN)	BE-AR-000012231
Наименование на нотифицирания орган	DEKRA Certification B.V.
Идентификационен номер на нотифицирания орган	NB 0344
Номер на техническата документация	TD0015
Име(на) на продукта и търговско(и) наименование(я)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Код(ове) на продукта/продуктова гама и описание	**European Part Number** / **Manufacturing Part Number** / **Product description** D134701 / D-1347-01-S / THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter D134702 / D-1347-02-S D134703 / D-1347-03-S D134801 / D-1348-01-S / THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter D134802 / D-1348-02-S D134803 / D-1348-03-S D134804 / D-1348-04-S D134805 / D-1348-05-S
Предназначение	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Класификация	Клас III (Приложение VIII, Правило 7)

Български (Bulgarian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ДЕКЛАРАЦИЯ НА ЕС ЗА СЪОТВЕТСТВИЕ

	Вижте Приложение 1
GMDN код	61785
EMDN код	C020301
Стойност на базов UDI-DI	08468350a0010EQ
RoHS	Ние Biosense Webster, Inc., с настоящото декларираме, че горепосочените медицински изделия съответстват на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 година относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване.

Тази декларация на ЕС за съответствие се издава изцяло на отговорността на производителя.

Ние, Biosense Webster, Inc., с настоящото декларираме, че горепосочените медицински изделия съответстват на Регламент (ЕС) 2017/745 за медицинските изделия.

Тази декларация се прави въз основа на:

Сертификат за оценка на техническата документация на ЕС номер 3903009TD01, издаден от нотифицирания орган, посочен по-горе, в съответствие с приложение IX, глава II към Регламент (ЕС) 2017/745 за медицинските изделия.

Сертификат за система за качество на ЕС номер 3903009CE01, издаден от нотифицирания орган, посочен по-горе, в съответствие с приложение IX, глави I и III към Регламент (ЕС) 2017/745 за медицинските изделия.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director of Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Забележка: За декларация за съответствие на английски език се счита „EN Master DoC“. Подписите с дата в „EN Master DoC“ в същото време потвърждават валидността на преведените декларации за съответствие.

Lietuvių k. (Lithuanian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ES ATITIKTIES DEKLARACIJA

Gamintojo pavadinimas	Biosense Webster, Inc.
Gamintojo adresas	31 Technology Drive, Suite 200, Irvine, California 92618 USA
Gamintojo unikalusis registracijos numeris (SRN)	US-MF-000014219
Įgaliotojo atstovo pavadinimas ir adresas	Biosense Webster A Division of Johnson & Johnson Medical NV/SA Leonardo da Vincilaan 15 1831 Diegem, Belgium
Įgaliotojo atstovo unikalusis registracijos numeris (SRN)	BE-AR-000012231
Notifikuotosios įstaigos pavadinimas	DEKRA Certification B.V.
Notifikuotosios įstaigos identifikacinis numeris	NB 0344
Techninės dokumentacijos Nr.	TD0015
Gaminio ir prekybinis pavadinimas (-ai)	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter
Gaminio kodas (-ai) / gaminio kategorija ir aprašas	See table below
Klasifikavimas	THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and, when used in conjunction with an RF generator, for cardiac ablation. THERMOCOOL SMARTTOUCH™ SF Uni-Directional and Bi-Directional Navigation Catheter provides 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.
Klasifikavimas	klasė III (priedas VIII, taisyklė 7)
GMDN kodas	61785

European Part Number	Manufacturing Part Number	Product description
D134701	D-1347-01-S	THERMOCOOL SMARTTOUCH™ SF Uni-Directional Navigation Catheter
D134702	D-1347-02-S	
D134703	D-1347-03-S	
D134801	D-1348-01-S	THERMOCOOL SMARTTOUCH™ SF Bi-Directional Navigation Catheter
D134802	D-1348-02-S	
D134803	D-1348-03-S	
D134804	D-1348-04-S	
D134805	D-1348-05-S	

Lietuvių k. (Lithuanian)

Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ES ATITIKTIES DEKLARACIJA

EMDN kodas	C020301
Bazinio UDI-DI vertė	08468350a0010EQ
RoHS	Mes, Biosense Webster, Inc., šiuo dokumentu pareiškiame, kad pirmiau nurodyta (-os) medicinos priemonės (-ės) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvą 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo.

Už šios ES atitikties deklaracijos išdavimą atsakingas tik gamintojas.

We, Biosense Webster, Inc., hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.

This declaration is made on the basis of:

EU Technical Documentation Assessment Certificate Number3903009TD01, issued by the Notified Body stated above, in accordance with Annex IX, Chapter II of the Medical Device Regulation (EU) 2017/745.

EU Quality System Certificate Number 3903009CE01, issued by the Notified Body stated above, in accordance with Annex IX, Chapters I and III of Medical Device Regulation (EU) 2017/745.

SIGNATURE SECTION			
Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	
Name/Title	Diana Bordley Sr. Director Regulatory Affairs		
Signature		**Date**	
Name/Title	Maria Jose Arana Sr. Director of Quality Compliance		
	Manufacturer's Person Responsible for Regulatory Compliance		

Pastaba. Atitikties deklaracija anglų kalba laikoma „pagrindine EN atitikties deklaracija". „Pagrindinėje EN atitikties deklaracijoje" esantys parašai su data nurodo, kad tuo pačiu metu galioja išverstos atitikties deklaracijos.