

English							
 <p><b>EU DECLARATION OF CONFORMITY</b></p>							
<b>Manufacturer's Name</b>	Biosense Webster, Inc.						
<b>Manufacturer's Address</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
<b>Authorized Representative's Name and Address</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
<b>Notified Body Name</b>	DEKRA Certification B.V.						
<b>Notified Body Identification Number</b>	0344						
<b>Product and Trade Name (s)</b>	SMARTABLATE™ System Interface Cable						
<b>Basic UDI-DI value</b>	08468350a0003ET						
<b>Product Code (s) Product Range and Description</b>	<table border="1"> <thead> <tr> <th>European Catalogue Number</th> <th>Manufacturing Part Number</th> </tr> </thead> <tbody> <tr> <td>D130302</td> <td>D-1303-02-S</td> </tr> <tr> <td>D130303</td> <td>D-1303-03-S</td> </tr> </tbody> </table>	European Catalogue Number	Manufacturing Part Number	D130302	D-1303-02-S	D130303	D-1303-03-S
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	D130302	D-1303-02-S					
D130303	D-1303-03-S						
<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>							
<b>Intended Purpose</b>	These Cables provide a means to connect a Biosense Webster electrophysiology catheter, external reference patch, or sheath to the appropriate equipment. The Cables may be re-used subject to the cleaning and sterilization restrictions in this document.						
<b>Classification</b>	Class Is (Annex VIII, Rule 1)						
<b>GMDN Code</b>	47487 – Electrical-only medical device connection cable, reusable						
<b>Technical Documentation Number</b>	TD0022						
<b>RoHS</b>	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 restriction of the use of certain hazardous substances in electrical and electronic equipment.						

<p><b>English</b></p>  <p><b>EU DECLARATION OF CONFORMITY</b></p>
<p>We, Biosense Webster Inc, hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.</p> <p>This declaration is made on the basis of:</p> <p>EU Quality System Certificate Number 3828594CE01, issued by the Notified Body stated above, in accordance with Annex IX, Chapters I and III of Medical Device Regulation (EU) 2017/745.</p> <p><b>This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.</b></p>

SIGNATURE SECTION			
Place of Issue	Refer to Manufacturer's Address above		
Signature	[Redacted]	Date	September 13, 2021
Name/Title	Diana Bordley Sr. Director of Regulatory Affairs		
Signature	[Redacted]	Date	SEP 20th 2021
Name/Title	Maria Jose Arana Senior Director of Quality and Compliance <b>Manufacturer's Person Responsible for Regulatory Compliance</b>		

Български (Bulgarian)							
ДЕКЛАРАЦИЯ НА ЕС ЗА СЪОТВЕТСТВИЕ							
Наименование на производителя	Biosense Webster, Inc.						
Адрес на производителя	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Наименование и адрес на упълномощения представител	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Наименование на нотифицирания орган	DEKRA Certification B.V.						
Идентификационен номер на нотифицирания орган	0344						
Номер на техническата документация	TD0022						
Име(на) на продукта и търговско(и) наименование(я)	SMARTABLATE™ System Interface Cable						
Код(ове) на продукта/продуктова гама и описание	European Catalogue Number	Manufacturing Part Number					
	D130302	D-1303-02-S					
	D130303	D-1303-03-S					
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Име на кабела</th> <th>Цел</th> <th>Производствени номера</th> </tr> </thead> <tbody> <tr> <td>Системен интерфейс кабел SMARTABLATE™</td> <td>Свързва терапевтичен катетър към генератор SMARTABLATE™.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>		Име на кабела	Цел	Производствени номера	Системен интерфейс кабел SMARTABLATE™	Свързва терапевтичен катетър към генератор SMARTABLATE™.
Име на кабела	Цел	Производствени номера					
Системен интерфейс кабел SMARTABLATE™	Свързва терапевтичен катетър към генератор SMARTABLATE™.	D-1303-02-S D-1303-03-S					
Предназначение	Тези кабели осигуряват връзка между електрофизиологичен катетър Biosense Webster, външната референтна лепенка или дезилето и съответното оборудване. Кабелите може да се използват многократно при спазване на посочените в						

**Български (Bulgarian)**

**ДЕКЛАРАЦИЯ НА ЕС ЗА СЪОТВЕТСТВИЕ**

	настоящия документ ограничения за почистване и стерилизация.
<b>Класификация</b>	Клас Is (Приложение Annex VIII, Правило Rule 1)
<b>GMDN код</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Стойност на базов UDI-DI</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Тази декларация на ЕС за съответствие се издава изцяло на отговорността на производителя.</b>	
Ние, Biosense Webster, Inc., с настоящото декларираме, че горепосоченото медицинско изделие съответства на Регламент (ЕС) 2017/745 за медицинските изделия. Тази декларация се прави въз основа на: Сертификат за система за качество на ЕС номер 3828594CE01, издаден от нотифицирания орган, посочен по-горе, в съответствие с приложение IX, глави I и III към Регламент (ЕС) 2017/745 за медицинските изделия.	

Česky (Czech)

**EU PROHLÁŠENÍ O SHODĚ**

<b>Název výrobce</b>	Biosense Webster, Inc.							
<b>Adresa výrobce</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA							
<b>Název a adresa zplnomocněného zástupce</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium							
<b>Název oznámeného subjektu</b>	DEKRA Certification B.V.							
<b>Identifikační číslo oznámeného subjektu</b>	0344							
<b>Číslo technické dokumentace</b>	TD0022							
<b>Název (názy) a obchodní název (názy) výrobku</b>	SMARTABLATE™ System Interface Cable							
<b>Kód(y) výrobku/výrobků / řada a popis výrobku/výrobků</b>	European Catalogue Number	Manufacturing Part Number						
	D130302	D-1303-02-S						
	D130303	D-1303-03-S						
	The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.							
<table border="1"><thead><tr><th>Název kabelu</th><th>Účel</th><th>Výrobní čísla</th></tr></thead><tbody><tr><td>Propojovací kabel systému SMARTABLATE™</td><td>Připojuje terapeutický katétr ke generátoru SMARTABLATE™.</td><td>D-1303-02-S D-1303-03-S</td></tr></tbody></table>	Název kabelu	Účel	Výrobní čísla	Propojovací kabel systému SMARTABLATE™	Připojuje terapeutický katétr ke generátoru SMARTABLATE™.	D-1303-02-S D-1303-03-S		
Název kabelu	Účel	Výrobní čísla						
Propojovací kabel systému SMARTABLATE™	Připojuje terapeutický katétr ke generátoru SMARTABLATE™.	D-1303-02-S D-1303-03-S						
<b>Určený účel</b>	Tyto kabely umožňují propojení elektrofyziologického katétru, externí referenční elektrody nebo zavaděče Biosense Webster s vhodným příslušenstvím. Kabely lze při splnění podmínek čištění a sterilizace uvedených v tomto dokumentu používat opakovaně.							
<b>Klasifikace</b>	Třída Is (příloha Annex VIII, pravidlo Rule 1)							

<b>Česky (Czech)</b>	
<b>EU PROHLÁŠENÍ O SHODĚ</b>	
<b>Kód GMDN</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Hodnota základního identifikátoru UDI-DI</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Toto prohlášení o shodě EU se vydává na výhradní odpovědnost výrobce.</b>	
<p>My, Biosense Webster, Inc., tímto prohlašujeme, že výše uvedený zdravotnický prostředek splňuje požadavky nařízení o zdravotnických prostředcích (EU) 2017/745.</p> <p>Toto prohlášení vychází z:</p> <p>certifikátu systému kvality EU číslo 3828594CE01, vydaného výše uvedeným oznámeným subjektem v souladu s kapitolami I a III přílohy IX nařízení o zdravotnických prostředcích (EU) 2017/745.</p>	

<b>Dansk (Danish)</b>		
<b>EU-OVERENSSTEMMELSESERKLÆRING</b>		
<b>Fabrikantens navn</b>	Biosense Webster, Inc.	
<b>Fabrikantens adresse</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA	
<b>Autoriseret repræsentants navn og adresse</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium	
<b>Navn på det bemyndigede organ</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium	
<b>Bemyndiget organs identifikationsnummer</b>	0344	
<b>Teknisk dokumentationsnummer</b>	TD0022	
<b>Produkt- og handelsnavn(e)</b>	SMARTABLATE™ System Interface Cable	
<b>Produktkode(r)/produksortiment og -beskrivelse</b>	European Catalogue Number	Manufacturing Part Number
	D130302	D-1303-02-S
	D130303	D-1303-03-S
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>	
	Kablets navn	Formål
	SMARTABLATE™-systeminterfacekabel	Forbinder et terapeutisk kateter med en SMARTABLATE™-generator.
		Produktionsnumre D-1303-02-S D-1303-03-S
<b>Erklæret formål</b>	Disse kabler giver mulighed for at forbinde et elektrofysiologisk kateter, eksterne referenceelektroder eller en stilette fra Biosense Webster med det relevante udstyr. Kablerne kan genanvendes under forudsætning af, at rengørings- og steriliseringsvejledningen i dette dokument overholdes.	

Dansk (Danish)

**EU-OVERENSSTEMMELSESERKLÆRING**

<b>Klassificering</b>	Klasse Is (Bilag Annex VIII, Regel Rule 1)
<b>GMDN-kode</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Grundlæggende UDI-DI-værdi</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Denne EU-overensstemmelseserklæring udstedes på fabrikantens eneansvar.</b>	
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-kvalitetssystemcertifikatnummer 3828594CE01, udstedt af det bemyndigede organ, der er anført ovenfor, i overensstemmelse med bilag IX, kapitel I og III i forordning (EU) 2017/745 om medicinsk udstyr.	

<b>Deutsch (German)</b>							
<b>EU-KONFORMITÄTSERKLÄRUNG</b>							
<b>Name des Herstellers</b>	Biosense Webster, Inc.						
<b>Adresse des Herstellers</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
<b>Name und Adresse des bevollmächtigten Vertreters</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
<b>Name der Benannten Stelle</b>	DEKRA Certification B.V.						
<b>Identifikationsnummer der Benannten Stelle</b>	0344						
<b>Nummer der technischen Dokumentation</b>	TD0022						
<b>Produkt- und Handelsname</b>	SMARTABLATE™ System Interface Cable						
<b>Produktcode(s)/Produktpalette und Beschreibung</b>	<table border="1"> <thead> <tr> <th>European Catalogue Number</th> <th>Manufacturing Part Number</th> </tr> </thead> <tbody> <tr> <td>D130302</td> <td>D-1303-02-S</td> </tr> <tr> <td>D130303</td> <td>D-1303-03-S</td> </tr> </tbody> </table>	European Catalogue Number	Manufacturing Part Number	D130302	D-1303-02-S	D130303	D-1303-03-S
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Kabelname	Zweck	Herstellungsnummern					
SMARTABLATE™ System Verbindungskabel	Verbindung zwischen therapeutischem Katheter und SMARTABLATE™ Generator.	D-1303-02-S D-1303-03-S					
<b>Zweckbestimmung</b>	Mithilfe dieser Kabel kann ein elektrophysiologischer Katheter, ein externer Referenzsensor oder eine Schleuse von Biosense Webster an ein geeignetes Gerät angeschlossen werden. Die Kabel können – unter Beachtung der in diesem Dokument erläuterten Beschränkungen für die Reinigung und Sterilisation – wiederverwendet werden.						

Deutsch (German)

**EU-KONFORMITÄTSERKLÄRUNG**

<b>Klassifizierung</b>	Klasse Is (Anhang Annex VIII, Regel Rule 1)
<b>GMDN-Code</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Basis-UDI-DI-Wert</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Diese EU-Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.</b>	
Wir, Biosense Webster, Inc., erklären hiermit, dass das oben aufgeführte Medizinprodukt die Verordnung (EU) 2017/745 über Medizinprodukte erfüllt. Diese Erklärung wird auf folgender Grundlage ausgestellt: EU-Zertifikatsnummer für Qualitätssicherungssysteme 3828594CE01, ausgestellt von der oben genannten Benannten Stelle, in Übereinstimmung mit Anhang IX, Kapitel I und III der Verordnung (EU) 2017/745 über Medizinprodukte.	

Ελληνικά (Greek)							
ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ							
Όνομα κατασκευαστή	Biosense Webster, Inc.						
Διεύθυνση κατασκευαστή	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Όνομα και διεύθυνση Εξουσιοδοτημένου Αντιπροσώπου	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Όνομα Κοινοποιημένου Οργανισμού	DEKRA Certification B.V.						
Αριθμός Ταυτοποίησης Κοινοποιημένου Οργανισμού	0344						
Αριθμός τεχνικού φακέλου	TD0022						
Όνομασία(ες) προϊόντος και εμπορική(ές) επωνυμία(ες)	SMARTABLATE™ System Interface Cable						
Κωδικός(οί) προϊόντος(ων)/Σειρά και περιγραφή προϊόντων	European Catalogue Number	Manufacturing Part Number					
	D130302	D-1303-02-S					
	D130303	D-1303-03-S					
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Όνομα καλωδίου</th> <th>Σκοπός</th> <th>Αριθμοί παραγωγής</th> </tr> </thead> <tbody> <tr> <td>Καλώδιο διασύνδεσης συστήματος SMARTABLATE™</td> <td>Συνδέει έναν θεραπευτικό καθετήρα με μια γεννήτρια SMARTABLATE™.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>		Όνομα καλωδίου	Σκοπός	Αριθμοί παραγωγής	Καλώδιο διασύνδεσης συστήματος SMARTABLATE™	Συνδέει έναν θεραπευτικό καθετήρα με μια γεννήτρια SMARTABLATE™.
Όνομα καλωδίου	Σκοπός	Αριθμοί παραγωγής					
Καλώδιο διασύνδεσης συστήματος SMARTABLATE™	Συνδέει έναν θεραπευτικό καθετήρα με μια γεννήτρια SMARTABLATE™.	D-1303-02-S D-1303-03-S					
Προβλεπόμενη χρήση	Τα καλώδια αυτά παρέχουν ένα μέσο διασύνδεσης του καθετήρα ηλεκτροφυσιολογίας, του εξωτερικού εμβολώματος αναφοράς ή του θηκαριού της Biosense Webster με τον κατάλληλο εξοπλισμό. Τα καλώδια αυτό μπορούν να επαναχρησιμοποιηθούν, με την επιφύλαξη των περιορισμών όσον αφορά τον καθαρισμό και την						

<b>Ελληνικά (Greek)</b>	
<b>ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ</b>	
	αποστείρωση οι οποίοι αναφέρονται στο παρόν έγγραφο.
<b>Ταξινόμηση</b>	Κατηγορία Is (Παράρτημα Annex VIII, Κανόνας Rule 1)
<b>Κωδικός GMDN</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Τιμή βασικού UDI-DI</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Η παρούσα Δήλωση συμμόρφωσης ΕΕ εκδίδεται με την αποκλειστική ευθύνη του κατασκευαστή.</b>	
Εμείς, Biosense Webster, Inc., διά του παρόντος δηλώνουμε ότι το προαναφερόμενο ιατροτεχνολογικό προϊόν συμμορφώνεται με τον Κανονισμό για τα Ιατροτεχνολογικά Προϊόντα (ΕΕ) 2017/745.  Η παρούσα δήλωση πραγματοποιείται με βάση τον:  Αριθμό Πιστοποιητικού Συστήματος Ποιότητας ΕΕ 3828594CE01, που εκδόθηκε από τον Κοινοποιημένο Οργανισμό που δηλώνεται παραπάνω, σύμφωνα με το Παράρτημα ΙΧ, Κεφάλαια Ι και ΙΙΙ του Κανονισμού για τα Ιατροτεχνολογικά Προϊόντα (ΕΕ) 2017/745.	

Español (Spanish)							
DECLARACIÓN DE CONFORMIDAD DE LA UE							
Nombre del fabricante	Biosense Webster, Inc.						
Dirección del fabricante	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Nombre y dirección del representante autorizado	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Nombre del organismo notificado	DEKRA Certification B.V.						
Número de identificación del organismo notificado	0344						
Número de documentación técnica	TD0022						
Denominaciones y nombres comerciales del producto	SMARTABLATE™ System Interface Cable						
Código del producto/gama y descripción del producto	European Catalogue Number	Manufacturing Part Number					
	D130302	D-1303-02-S					
	D130303	D-1303-03-S					
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Nombre del cable</th> <th>Indicaciones</th> <th>N.º de fabricación</th> </tr> </thead> <tbody> <tr> <td>Cable de interfaz del sistema SMARTABLATE™</td> <td>Conecta un catéter terapéutico a un generador SMARTABLATE™.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>		Nombre del cable	Indicaciones	N.º de fabricación	Cable de interfaz del sistema SMARTABLATE™	Conecta un catéter terapéutico a un generador SMARTABLATE™.
Nombre del cable	Indicaciones	N.º de fabricación					
Cable de interfaz del sistema SMARTABLATE™	Conecta un catéter terapéutico a un generador SMARTABLATE™.	D-1303-02-S D-1303-03-S					
Finalidad prevista	Estos cables proporcionan un medio para conectar un catéter de electrofisiología, un parche de referencia externa o una vaina de Biosense Webster con el equipo apropiado. Los cables pueden volver a utilizarse si se tienen en cuenta las restricciones de esterilización y limpieza de este documento.						
Clasificación	Clase Is (anexo Annex VIII, regla Rule 1)						

**Español (Spanish)**

**DECLARACIÓN DE CONFORMIDAD DE LA UE**

**Código GMDN**

47487 – Electrical-only medical device connection cable, reusable

**Valor de UDI-DI básico**

08468350a0003ET

**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 el producto sanitario indicado anteriormente cumple el Reglamento sobre productos sanitarios (UE) 2017/745.

Esta declaración se realiza basándose en:

Número de certificado del sistema de calidad de la UE, 3828594CE01, 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.

<b>Eesti keel (Estonian)</b>			
<b>ELI VASTAVUSDEKLARATSIOON</b>			
<b>Tootja nimi</b>	Biosense Webster, Inc.		
<b>Tootja aadress</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA		
<b>Volitatud esindaja nimi ja aadress</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium		
<b>Teavitatud asutuse nimi</b>	DEKRA Certification B.V.		
<b>Teavitatud asutuse identifitseerimisnumber</b>	0344		
<b>Tehnilise dokumentatsiooni number</b>	TD0022		
<b>Toote nimetus(ed) ja kaubanimi (-nimed)</b>	SMARTABLATE™ System Interface Cable		
<b>Tootekood(id) / tooteseeria ja kirjeldus</b>	European Catalogue Number	Manufacturing Part Number	
	D130302	D-1303-02-S	
	D130303	D-1303-03-S	
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>		
	Kaabli nimi	Eesmärk	Tootmisnumbrid
	SMARTABLATE™ süsteemi liideskaabel	Ühendab terapeutilise kateetri SMARTABLATE™ generaatoriga.	D-1303-02-S D-1303-03-S
<b>Sihotstarve</b>	Kaablite abil saab Biosense Websteri elektrofüsioloogilise kateetri, välise võrdlusplaastri või kanüüli ühendada sobiva seadmega. Neid kaableid võib taaskasutada, järgides selles dokumendis toodud puhastamise ja steriliseerimise piiranguid.		
<b>Liigitamine</b>	Klass Is (lisa Annex VIII, reegel Rule 1)		

**Eesti keel (Estonian)****ELi VASTAVUSDEKLARATSIOON**

<b>GMDN-kood</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Põhi-UDI-DI väärtus</b>	08468350a0003ET
<b>RoHS</b>	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 vastab meditsiiniseadmete määrusele (EL) 2017/745.  
See deklaratsioon põhineb järgmisel:  
ELi kvaliteedisüsteemi sertifikaat nr 3828594CE01, mille on välja andnud ülalnimetatud teavitatud asutus kooskõlas meditsiiniseadmete määruse (EL) 2017/745 IX lisa I ja III peatükiga.

Suomi (Finnish)			
EU-VAATIMUSTENMUKAISUUSVAKUUTUS			
Valmistajan nimi	Biosense Webster, Inc.		
Valmistajan osoite	31 Technology Drive, Suite 200 Irvine, California 92618 USA		
Valtuutetun edustajan nimi ja osoite	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium		
Ilmoitetun laitoksen nimi	DEKRA Certification B.V.		
Ilmoitetun laitoksen tunnistenumero	0344		
Teknisen asiakirjan numero	TD0022		
Tuote- ja kaupan nimi (tai -nimet)	SMARTABLATE™ System Interface Cable		
Tuotekoodi(t) / tuotetyyppi ja -kuvaus	European Catalogue Number	Manufacturing Part Number	
	D130302	D-1303-02-S	
	D130303	D-1303-03-S	
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>		
	Kaapelin nimi	Käyttötarkoitus	Valmistusnumerot
	SMARTABLATE™-järjestelmän liitäntäkaapeli	Liittää terapeuttisen katetrin SMARTABLATE™-generaattoriin.	D-1303-02-S D-1303-03-S
Käyttötarkoitus	Näitä kaapeleita käytetään elektrofysiologisen Biosense Webster -katetrin, ulkoisen referenssielektrodin tai holkin liittämiseen sopiviin laitteistoihin. Kaapeleita voidaan käyttää uudelleen, jos jäljempänä esitetyt sterilointia koskevat rajoitukset huomioidaan.		
Luokitus	Luokka Is (liite Annex VIII, sääntö Rule 1)		

**Suomi (Finnish)**

**EU-VAATIMUSTENMUKAISUUSVAKUUTUS**

<b>GMDN-koodi</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Basic UDI-DI -arvo</b>	08468350a0003ET
<b>RoHS</b>	Me Biosense Webster, Inc. täten vakuutamme, että edellä mainittu lääkinällinen 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.
<b>Tämä EU-vaatimustenmukaisuusvakuutus annetaan valmistajan yksinomaisella vastuulla.</b>	
Me Biosense Webster, Inc. täten vakuutamme, että edellä mainittu lääkinällinen laite on lääkinällisiä laitteita koskevan asetuksen (EU) 2017/745 mukainen. Tämä ilmoitus perustuu: EU:n laadunhallintajärjestelmän sertifikaattinumeroon 3828594CE01, jonka on myöntänyt yllä ilmoitettu laitos lääkinällisiä laitteita koskevan asetuksen (EU) 2017/745 liitteen IX lukujen I ja III mukaisesti.	

Français (French)							
DÉCLARATION DE CONFORMITÉ UE							
Nom du fabricant	Biosense Webster, Inc.						
Adresse du fabricant	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Nom et adresse du mandataire	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Nom de l'organisme notifié	DEKRA Certification B.V.						
Numéro d'identification de l'organisme notifié	0344						
Numéro de documentation technique	TD0022						
Nom(s) et dénomination(s) commerciale(s) du produit	SMARTABLATE™ System Interface Cable						
Code(s) du produit/Gamme et description du produit	European Catalogue Number	Manufacturing Part Number					
	D130302	D-1303-02-S					
	D130303	D-1303-03-S					
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Nom du câble</th> <th>Objet</th> <th>Numéros de fabrication</th> </tr> </thead> <tbody> <tr> <td>Câble d'interface du système SMARTABLATE™</td> <td>Permet de raccorder un cathéter thérapeutique à un générateur SMARTABLATE™.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>		Nom du câble	Objet	Numéros de fabrication	Câble d'interface du système SMARTABLATE™	Permet de raccorder un cathéter thérapeutique à un générateur SMARTABLATE™.
Nom du câble	Objet	Numéros de fabrication					
Câble d'interface du système SMARTABLATE™	Permet de raccorder un cathéter thérapeutique à un générateur SMARTABLATE™.	D-1303-02-S D-1303-03-S					
Destination	<p>Ces câbles permettent de connecter un cathéter d'électrophysiologie Biosense Webster, un patch de référence externe ou une gaine à l'équipement approprié. Les câbles peuvent être réutilisés sous réserve d'observation des restrictions stipulées dans ce document en matière de nettoyage et de stérilisation.</p>						

**Français (French)**

**DÉCLARATION DE CONFORMITÉ UE**

<b>Classification</b>	Classe Is (Annexe Annex VIII, règle Rule 1)
<b>Code GMDN</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Valeur de l'IUD-ID de base</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Cette déclaration de conformité UE est délivrée sous la responsabilité exclusive du fabricant.</b>	
Nous, Biosense Webster, Inc., déclarons par les présentes que le dispositif médical énuméré ci-dessus est conforme au règlement (UE) 2017/745 relatif aux dispositifs médicaux. Cette déclaration est faite sur la base de : Numéro de certificat UE relatif au système qualité 3828594CE01, délivré par l'organisme notifié susmentionné, conformément à l'Annexe IX, chapitres I et III du règlement (UE) 2017/745 relatif aux dispositifs médicaux.	

Hrvatski (Croatian)		
EU IZJAVA O SUKLADNOSTI		
Naziv proizvođača	Biosense Webster, Inc.	
Adresa proizvođača	31 Technology Drive, Suite 200 Irvine, California 92618 USA	
Naziv i adresa ovlaštenog predstavnika	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium	
Naziv prijavljenog tijela	DEKRA Certification B.V.	
Identifikacijski broj prijavljenog tijela	0344	
Broj tehničke dokumentacije	TD0022	
Nazivi proizvoda i trgovačka imena proizvoda	SMARTABLATE™ System Interface Cable	
Šifre proizvoda / asortiman proizvoda i opis	European Catalogue Number	Manufacturing Part Number
	D130302	D-1303-02-S
	D130303	D-1303-03-S
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>	
Naziv kabela	Namjena	Broj proizvoda
Kabel za sučelje sustava SMARTABLATE™	Povezuje terapijski kateter i generator SMARTABLATE™.	D-1303-02-S D-1303-03-S
Namjena	Ovi kabele služe kao sredstvo za povezivanje elektrofiziološkog katetera tvrtke Biosense Webster, vanjskog referentnog jastučića ili ovojnice s odgovarajućom opremom. Kabele se smiju ponovno upotrijebiti pod uvjetom da se pridržavate uputa za čišćenje i sterilizaciju navedenih u ovom dokumentu.	
Klasifikacija	Klasa Is (Prilog Annex VIII, pravilo Rule 1)	
GMDN šifra	47487 – Electrical-only medical device connection cable,	

Hrvatski (Croatian)

**EU IZJAVA O SUKLADNOSTI**

	reusable
Vrijednost za osnovni UDI-ID	08468350a0003ET
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.
<b>Ova EU izjava o sukladnosti izdana je pod isključivom odgovornošću proizvođača.</b>	
Biosense Webster, Inc. izjavljuje da je gore navedeni medicinski proizvod usklađen s Uredbom (EU) 2017/745 o medicinskim proizvodima. Ova se izjava temelji na: EU potvrdi o sustavu upravljanja kvalitetom broj 3828594CE01, koju je izdalo gore navedeno prijavljeno tijelo u skladu s Prilogom IX. poglavljima I. i III. Uredbe (EU) 2017/745 o medicinskim proizvodima.	

<b>Magyar (Hungarian)</b>			
<b>EU-MEGFELELŐSÉGI NYILATKOZAT</b>			
<b>Gyártó neve</b>	Biosense Webster, Inc.		
<b>Gyártó címe</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA		
<b>Meghatalmazott képviselő neve és címe</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium		
<b>Bejelentett szervezet neve</b>	DEKRA Certification B.V.		
<b>Bejelentett szervezet azonosítószáma</b>	0344		
<b>Műszaki dokumentáció száma</b>	TD0022		
<b>Terméknév/terméknevek és kereskedelmi név/kereskedelmi nevek</b>	SMARTABLATE™ System Interface Cable		
<b>Termékkód(ok)/termékskála és -leírás</b>	European Catalogue Number	Manufacturing Part Number	
	D130302	D-1303-02-S	
	D130303	D-1303-03-S	
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>		
	Kábel neve	Rendeltetés	Gyártási számok
	SMARTABLATE™ rendszer csatlakoztatókábel	Egy terápiás katétert egy SMARTABLATE™ generátorhoz csatlakoztat.	D-1303-02-S D-1303-03-S
<b>Rendeltetés</b>	A kábelek a Biosense Webster elektrofiziológiai katéter, a külső referenciatapasz vagy -hüvely megfelelő berendezéshez való csatlakoztatására szolgálnak. A kábelek a dokumentumban leírt tisztítási és sterilizálási feltételek betartása mellett újrafelhasználhatók.		
<b>Osztályozás</b>	Is. osztály (Annex VIII. melléklet, Rule 1. szabály)		

**Magyar (Hungarian)**

**EU-MEGFELELŐSÉGI NYILATKOZAT**

<b>GMDN-kód</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Alapvető UDI-DI értéke</b>	08468350a0003ET
<b>RoHS</b>	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 megfelel az orvostechnikai eszközökről szóló (EU) 2017/745 rendeletnek.  
A jelen nyilatkozat alapja:  
A minőségirányítási rendszer EU-tanúsítványának száma: 3828594CE01, amelyet a fent megnevezett bejelentett szervezet adott ki az orvostechnikai eszközökről szóló (EU) 2017/745 rendelet IX. mellékletének I. és III. fejezetével összhangban.

Italiano (Italian)			
<b>DICHIARAZIONE DI CONFORMITÀ UE</b>			
<b>Nome del fabbricante</b>	Biosense Webster, Inc.		
<b>Indirizzo del fabbricante</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA		
<b>Nome e indirizzo del mandatario</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium		
<b>Nome dell'organismo notificato</b>	DEKRA Certification B.V.		
<b>Numero di identificazione dell'organismo notificato</b>	0344		
<b>Numero della documentazione tecnica</b>	TD0022		
<b>Nomi dei prodotti e denominazioni commerciali</b>	SMARTABLATE™ System Interface Cable		
<b>Codici del prodotto/Gamma e descrizione del prodotto</b>	European Catalogue Number	Manufacturing Part Number	
	D130302	D-1303-02-S	
	D130303	D-1303-03-S	
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>		
	Nome del cavo	Finalità	Numeri di produzione
	Cavo di interfaccia del sistema SMARTABLATE™	Collega un catetere terapeutico a un generatore SMARTABLATE™.	D-1303-02-S D-1303-03-S
<b>Scopo previsto</b>	Questi cavi costituiscono un mezzo di collegamento tra un catetere per elettrofisiologia Biosense Webster, un cerotto di riferimento esterno o una guaina e l'apparecchiatura appropriata. I cavi possono essere riutilizzati a condizione che vengano rispettate le restrizioni di pulizia e sterilizzazione descritte nel presente documento.		
<b>Classificazione</b>	Classe Is (Appendice Annex VIII, Regola Rule 1)		

<b>Italiano (Italian)</b>	
<b>DICHIARAZIONE DI CONFORMITÀ UE</b>	
<b>Codice GMDN</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Valore UDI-DI di base</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Questa Dichiarazione di conformità UE è rilasciata sotto l'esclusiva responsabilità del fabbricante.</b>	
<p>Noi di Biosense Webster, Inc. con la presente dichiariamo che il dispositivo medico indicato sopra è conforme al Regolamento sui dispositivi medici (UE) 2017/745.</p> <p>Questa dichiarazione è effettuata sulla base di:</p> <p>Numero del certificato del sistema di qualità UE 3828594CE01, rilasciato dall'organismo notificato indicato sopra, in conformità all'Appendice IX, Capitoli I e III del Regolamento sui dispositivi medici (UE) 2017/745.</p>	

Lietuvių k. (Lithuanian)

### ES ATITIKTIES DEKLARACIJA

<b>Gamintojo pavadinimas</b>	Biosense Webster, Inc.	
<b>Gamintojo adresas</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA	
<b>Igaliotojo atstovo pavadinimas ir adresas</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium	
<b>Notifikuotosios įstaigos pavadinimas</b>	DEKRA Certification B.V.	
<b>Notifikuotosios įstaigos identifikacinis numeris</b>	0344	
<b>Techninės dokumentacijos Nr.</b>	TD0022	
<b>Gaminio ir prekybinis pavadinimas (-ai)</b>	SMARTABLATE™ System Interface Cable	
<b>Gaminio kodas (-ai) / gaminio kategorija ir aprašas</b>	European Catalogue Number	Manufacturing Part Number
	D130302	D-1303-02-S
	D130303	D-1303-03-S
	The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.	
<b>Numatyta paskirtis</b>	Šie kabeliai skirti „Biosense Webster“ elektrofiziologiniam kateteriui, išoriniam referenciniam pleistrui arba movai prijungti prie atitinkamos įrangos. Kabelius galima naudoti pakartotinai, jei laikomasi šiame dokumente pateiktų valymo ir sterilizavimo apribojimų.	
<b>Klasifikavimas</b>	Is klasė (Annex VIII priedas, Rule 1 taisyklė)	

Lietuvių k. (Lithuanian)

**ES ATITIKTIES DEKLARACIJA**

<b>GMDN kodas</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Bazinio UDI-DI vertė</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Už šios ES atitikties deklaracijos išdavimą atsakingas tik gamintojas.</b>	
Mes, Biosense Webster, Inc., šiuo dokumentu pareiškiame, kad pirmiau nurodyta medicinos priemonė atitinka Medicinos priemonių reglamentą (ES) 2017/745. Ši deklaracija parengta remiantis: ES kokybės sistemos sertifikatu Nr. 3828594CE01, kurį išdavė pirmiau nurodyta notifikuotoji įstaiga pagal Medicinos priemonių reglamento (ES) 2017/745 IX priedo I ir III skyrius.	

Latviešu (Latvian)							
ES ATBILSTĪBAS DEKLARĀCIJA							
Ražotāja nosaukums	Biosense Webster, Inc.						
Ražotāja adrese	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Pilnvarotā pārstāvja nosaukums un adrese	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Paziņotās struktūras nosaukums	DEKRA Certification B.V.						
Paziņotās struktūras identifikācijas numurs	0344						
Tehniskās dokumentācijas numurs	TD0022						
Izstrādājuma nosaukums un tirdzniecības nosaukums (-i)	SMARTABLATE™ System Interface Cable						
Izstrādājuma kods(-i) / Izstrādājumu klāsts un apraksts	European Catalogue Number	Manufacturing Part Number					
	D130302	D-1303-02-S					
	D130303	D-1303-03-S					
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Kabeļa nosaukums</th> <th>Mērķis</th> <th>Ražošanas numuri</th> </tr> </thead> <tbody> <tr> <td>SMARTABLATE™ sistēmas saskarnes kabelis</td> <td>Savieno terapeitisko katetru ar SMARTABLATE™ ģeneratoru.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>		Kabeļa nosaukums	Mērķis	Ražošanas numuri	SMARTABLATE™ sistēmas saskarnes kabelis	Savieno terapeitisko katetru ar SMARTABLATE™ ģeneratoru.
Kabeļa nosaukums	Mērķis	Ražošanas numuri					
SMARTABLATE™ sistēmas saskarnes kabelis	Savieno terapeitisko katetru ar SMARTABLATE™ ģeneratoru.	D-1303-02-S D-1303-03-S					
Paredzētais nolūks	Šie kabeļi dod iespēju savienot Biosense Webster elektrofizioloģijas katetru, ārējās atsaucis spilventiņu vai apvalku ar piemērotu aprīkojumu. Kabeļus var izmantot atkārtoti, ja ievēro šajā dokumentā minētos tīrīšanas un sterilizēšanas ierobežojumus.						
Klasifikācija	Klase Is (Pielikums Annex VIII, Noteikums Rule 1)						

Latviešu (Latvian)

**ES ATBILSTĪBAS DEKLARĀCIJA**

<b>GMDN kods</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Pamata UDI-DI vērtība</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Par šīs ES atbilstības deklarācijas izdošanu pilnībā ir atbildīgs ražotājs.</b>	
Mēs, Biosense Webster, Inc., ar šo apliecinām, ka iepriekšminētā medicīniskā ierīce atbilst Medicīnisko ierīču regulai (ES) 2017/745. Šīs deklarācijas sagatavošanas pamats ir: ES kvalitātes sistēmas sertifikāts numur 3828594CE01, ko izdevusi iepriekšminētā paziņotā struktūra saskaņā ar Medicīnas ierīču regulas (ES) 2017/745 IX pielikuma I nodaļu un III nodaļu.	

<b>Nederlands (Dutch)</b>							
<b>EU-CONFORMITEITSVERKLARING</b>							
<b>Naam fabrikant</b>	Biosense Webster, Inc.						
<b>Adres fabrikant</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
<b>Naam en adres gemachtigde</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
<b>Naam aangemelde instantie</b>	DEKRA Certification B.V.						
<b>Identificatienummer aangemelde instantie</b>	0344						
<b>Technisch documentatienummer</b>	TD0022						
<b>Product- en handelsna(a)m(en)</b>	SMARTABLATE™ System Interface Cable						
<b>Productcode(s)/productgroep en -beschrijving</b>	<table border="1"> <thead> <tr> <th>European Catalogue Number</th> <th>Manufacturing Part Number</th> </tr> </thead> <tbody> <tr> <td>D130302</td> <td>D-1303-02-S</td> </tr> <tr> <td>D130303</td> <td>D-1303-03-S</td> </tr> </tbody> </table>	European Catalogue Number	Manufacturing Part Number	D130302	D-1303-02-S	D130303	D-1303-03-S
	European Catalogue Number	Manufacturing Part Number					
D130302	D-1303-02-S						
D130303	D-1303-03-S						
<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>							
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Naam kabel	Doel	Productienummers					
Interfacekabel SMARTABLATE™-systeem	Verbindt een therapeutische katheter met een SMARTABLATE™-generator.	D-1303-02-S D-1303-03-S					
<b>Beoogd doeleind</b>	Met deze kabels kunt u een elektrofysiologische katheter, externe referentiepatch of huls van Biosense Webster aan hiervoor geschikte apparatuur koppelen. Deze kabels kunnen opnieuw worden gebruikt mits de in dit document genoemde reinigings- en sterilisatiebeperkingen in acht worden genomen.						
<b>Classificatie</b>	Klasse Is (bijlage Annex VIII, regel Rule 1)						

**Nederlands (Dutch)**

**EU-CONFORMITEITSVERKLARING**

<b>GMDN-code</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Basic UDI-DI-waarde</b>	08468350a0003ET
<b>RoHS</b>	Wij Biosense Webster, Inc., verklaren hierbij dat hierboven vermeld medische hulpmiddel voldoet (hierboven vermelde 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.
<b>De EU-conformiteitsverklaring wordt verstrekt onder de exclusieve verantwoordelijkheid van de fabrikant.</b>	
Wij, Biosense Webster, Inc., verklaren hierbij dat hierboven vermeld medische hulpmiddel voldoet aan de verordening betreffende medische hulpmiddelen (EU) 2017/745. Deze verklaring is opgesteld op basis van: Certificaatnummer van het EU-kwaliteitssysteem 3828594CE01, 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.	

Norsk (Norwegian)							
EU-SAMSVARSERKLÆRING							
Produsentens navn	Biosense Webster, Inc.						
Produsentens adresse	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Autorisert representants navn og adresse	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Navn på kontrollorgan	DEKRA Certification B.V.						
Identifikasjonsnummer for kontrollorgan	0344						
Teknisk dokumentasjonsnummer	TD0022						
Produkt- og handelsnavn	SMARTABLATE™ System Interface Cable						
Produktkode(r)/produksortiment og -beskrivelse	European Catalogue Number	Manufacturing Part Number					
	D130302	D-1303-02-S					
	D130303	D-1303-03-S					
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Kabelnavn</th> <th>Formål</th> <th>Produsentnumre</th> </tr> </thead> <tbody> <tr> <td>Grensesnittkabel for SMARTABLATE™-systemet</td> <td>Kobler et terapeutisk kateter til en SMARTABLATE™-generator.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>		Kabelnavn	Formål	Produsentnumre	Grensesnittkabel for SMARTABLATE™-systemet	Kobler et terapeutisk kateter til en SMARTABLATE™-generator.
Kabelnavn	Formål	Produsentnumre					
Grensesnittkabel for SMARTABLATE™-systemet	Kobler et terapeutisk kateter til en SMARTABLATE™-generator.	D-1303-02-S D-1303-03-S					
Tiltenkt formål	Disse kablene er tilbehør for tilkobling av et Biosense Webster-elektrofysiologikateter, en ekstern referansepatch eller en hylse til aktuelt utstyr. Kablene kan gjenbrukes ved å følge rengjørings- og steriliseringsbegrensningene angitt i dette dokumentet.						
Klassifisering	Klasse Is (vedlegg Annex VIII, regel Rule 1)						
47487 – Electrical-only medical device connection cable, reusable	47487 – Electrical-only medical device connection cable, reusable						

**Norsk (Norwegian)**

**EU-SAMSVARSERKLÆRING**

<b>Grunnleggende UDI-DI-verdi</b>	08468350a0003ET
<b>RoHS</b>	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 den ovennevnte medisinske enheten er i samsvar med forordning (EU) 2017/745 om medisinsk utstyr.  
Denne erklæringen er oppgitt på grunnlag av:  
EU-sertifikatnummer for kvalitetssystem 3828594CE01, utstedt av kontrollorganet nevnt ovenfor, i samsvar med vedlegg IX, kapittel I og III i forordning (EU) 2017/745 om medisinsk utstyr.

Polski (Polish)		
DEKLARACJA ZGODNOŚCI UE		
Nazwa producenta	Biosense Webster, Inc.	
Adres producenta	31 Technology Drive, Suite 200 Irvine, California 92618 USA	
Nazwa i adres upoważnionego przedstawiciela	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium	
Nazwa jednostki notyfikowanej	DEKRA Certification B.V.	
Numer identyfikacyjny jednostki notyfikowanej	0344	
Numer dokumentacji technicznej	TD0022	
Nazwa(-y) produktu i nazwa(-y) handlowa(-e)	SMARTABLATE™ System Interface Cable	
Kod(y) produktu/zakres i opis produktu	European Catalogue Number	Manufacturing Part Number
	D130302	D-1303-02-S
	D130303	D-1303-03-S
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>	
Nazwa przewodu	Przeznaczenie	Numery produkcyjne
Przewód interfejsu systemu SMARTABLATE™	Łączy cewnik terapeutyczny z generatorem SMARTABLATE™.	D-1303-02-S D-1303-03-S
Przewidziane zastosowanie	Przewody umożliwiają połączenie cewnika elektrofizjologicznego firmy Biosense Webster, zewnętrznej łączy referencyjnej lub osłony z odpowiednim sprzętem. Przewody mogą być ponownie używane, o ile będą przestrzegane ograniczenia dotyczące czyszczenia i sterylizacji podane w niniejszym dokumencie.	
Klasyfikacja	Klasa Is (Aneks Annex VIII, Zasada Rule 1)	

Polski (Polish)

**DEKLARACJA ZGODNOŚCI UE**

**Kod GMDN**

47487 – Electrical-only medical device connection cable, reusable

**Wartość kodu Basic UDI-DI**

08468350a0003ET

**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 jest zgodny z rozporządzeniem w sprawie wyrobów medycznych (UE) 2017/745.

Oświadczenie to zostało złożone na podstawie:

Numer certyfikatu systemu jakości UE 3828594CE01, wydanego przez wyżej wymienioną jednostkę notyfikowaną, zgodnie z załącznikiem IX, rozdziałami I i III rozporządzenia w sprawie wyrobów medycznych (UE) 2017/745.

Português (Portuguese)							
DECLARAÇÃO DE CONFORMIDADE DA UE							
Nome do fabricante	Biosense Webster, Inc.						
Endereço do fabricante	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Nome e endereço do representante autorizado	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Nome do Organismo Notificado	DEKRA Certification B.V.						
Número de identificação do Organismo Notificado	0344						
Número da documentação técnica	TD0022						
Nome(s) comercial(is) e do produto	SMARTABLATE™ System Interface Cable						
Código(s) do produto/gama e descrição do produto	European Catalogue Number	Manufacturing Part Number					
	D130302	D-1303-02-S					
	D130303	D-1303-03-S					
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Nome do cabo</th> <th>Função</th> <th>Números de fabrico</th> </tr> </thead> <tbody> <tr> <td>Cabo de Interface do Sistema SMARTABLATE™</td> <td>Estabelece a ligação entre um cateter terapêutico e um Gerador SMARTABLATE™.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>		Nome do cabo	Função	Números de fabrico	Cabo de Interface do Sistema SMARTABLATE™	Estabelece a ligação entre um cateter terapêutico e um Gerador SMARTABLATE™.
Nome do cabo	Função	Números de fabrico					
Cabo de Interface do Sistema SMARTABLATE™	Estabelece a ligação entre um cateter terapêutico e um Gerador SMARTABLATE™.	D-1303-02-S D-1303-03-S					
Finalidade	Estes cabos oferecem um meio de se executar uma interface entre o cateter eletrofisiológico Biosense Webster, o patch de referência externo ou bainha e o equipamento apropriado. Os cabos podem ser reutilizados, mediante cumprimento das restrições de limpeza e esterilização indicadas neste documento.						
Classificação	Classe Is (Anexo Annex VIII, Regra Rule 1)						

**Português (Portuguese)**

**DECLARAÇÃO DE CONFORMIDADE DA UE**

<b>Código GMDN</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Valor UDI-DI básico</b>	08468350a0003ET
<b>RoHS</b>	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 eletrônicos.
<b>Esta Declaração de Conformidade da UE é emitida sob a exclusiva responsabilidade do Fabricante.</b>	
A Biosense Webster, Inc., declara pelo presente que o Dispositivo médico acima mencionado está em conformidade com o Regulamento (UE) 2017/745 relativo aos dispositivos médicos. Esta declaração é elaborada com base no: Número de certificado do sistema de qualidade da UE 3828594CE01, 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.	

Română (Romanian)

**DECLARAȚIE DE CONFORMITATE UE**

Denumire producător	Biosense Webster, Inc.		
Adresă producător	31 Technology Drive, Suite 200 Irvine, California 92618 USA		
Denumire și adresă reprezentant autorizat	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium		
Denumire organism notificat	DEKRA Certification B.V.		
Număr de identificare organism notificat	0344		
Număr documentație tehnică	TD0022		
Denumire produs și denumire(i) comercială(e)	SMARTABLATE™ System Interface Cable		
Cod(uri) produs/Gamă și descriere produs	European Catalogue Number	Manufacturing Part Number	
	D130302	D-1303-02-S	
	D130303	D-1303-03-S	
<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>			
	Denumire cablu	Scop	Numere de fabricare
	Cablu de interfață pentru sistem SMARTABLATE™	Conectează un cateter terapeutic la un generator SMARTABLATE™.	D-1303-02-S D-1303-03-S
Scop propus	Aceste cabluri oferă posibilitatea de conectare între un cateter de electrofiziologie Biosense Webster, un platură de referință extern sau o teacă la echipamentul corespunzător. Aceste cabluri pot fi refolosite conform restricțiilor legate de curățare și sterilizare din acest document.		
Clasificare	Clasă Is (Anexă Annex VIII, Regulă Rule 1)		

Română (Romanian)

**DECLARAȚIE DE CONFORMITATE UE**

<b>Cod GMDN</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Valoarea UDI-DI de bază</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Prezenta Declarație de conformitate UE este emisă pe răspunderea exclusivă a producătorului.</b>	
Noi, Biosense Webster, Inc., declarăm prin prezenta că dispozitivul medical de mai sus respectă Regulamentul (UE) 2017/745 privind dispozitivele medicale. Prezenta declarație se întocmește în baza: Certificatului privind sistemul de calitate UE cu numărul 3828594CE01, emis de organismul notificat de mai sus, în conformitate cu Anexa IX, Capitolele I și III din Regulamentul (UE) 2017/745 privind dispozitivele medicale.	

**Slovensky (Slovak)**

**EÚ VYHLÁSENIE O ZHODE**

<b>Názov výrobcu</b>	Biosense Webster, Inc.							
<b>Adresa výrobcu</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA							
<b>Názov a adresa splnomocneného zástupcu</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium							
<b>Názov notifikovanej osoby</b>	DEKRA Certification B.V.							
<b>Identifikačné číslo notifikovanej osoby</b>	0344							
<b>Číslo technickej dokumentácie</b>	TD0022							
<b>Názov(-vy) a obchodný(-é) názov(-vy) výrobku</b>	SMARTABLATE™ System Interface Cable							
<b>Kódy výrobkov/radvýrobkov a opis výrobkov</b>	European Catalogue Number	Manufacturing Part Number						
	D130302	D-1303-02-S						
	D130303	D-1303-03-S						
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p>							
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Názov kábla	Účel	Výrobné čísla						
Spojovací kábel systému SMARTABLATE™	Pripája terapeutický katéter ku generátoru SMARTABLATE™.	D-1303-02-S D-1303-03-S						
<b>Účel určenia</b>	Tieto káble umožňujú prepojenie elektrofyziologického katétra, externej referenčnej siete alebo zavádzača Biosense Webster s vhodným príslušenstvom. Káble sa môžu pri splnení podmienok čistenia a sterilizácie uvedených v tomto dokumente používať opakovane.							
<b>Klasifikácia</b>	Trieda Is (dodatok Annex VIII, pravidlo Rule 1)							

**Slovensky (Slovak)**

**EÚ VYHLÁSENIE O ZHODE**

<b>Kód GMDN</b>	47487 – Electrical-only medical device connection cable, reusable
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<b>Hodnota základného UDI-DI</b>	08468350a0003ET
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<b>RoHS</b>	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.
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**Toto EÚ vyhlásenie o zhode sa vydáva na výhradnú zodpovednosť výrobcu.**

My, Biosense Webster, Inc., týmto vyhlasujeme, že zdravotnícka pomôcka uvedená vyššie spĺňa podmienky nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.  
Toto vyhlásenie je uskutočnené na základe nasledovného:  
Číslo certifikátu systému kvality EÚ 3828594CE01, vydané notifikovanou osobou uvedenou vyššie v súlade s kapitolami I a III dodatku IX nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.

Slovenščina (Slovenian)							
IZJAVA EU O SKLADNOSTI							
Ime proizvajalca	Biosense Webster, Inc.						
Naslov proizvajalca	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Ime in naslov pooblaščenega predstavnika	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Ime priglšenega organa	DEKRA Certification B.V.						
Identifikacijska številka priglšenega organa	0344						
Številka tehnične dokumentacije	TD0022						
Ime(-na) izdelka in trgovsko(-a) ime(-na)	SMARTABLATE™ System Interface Cable						
Šifra(-e) izdelka / nabor izdelkov in opis	European Catalogue Number	Manufacturing Part Number					
	D130302	D-1303-02-S					
	D130303	D-1303-03-S					
	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Ime kabla</th> <th>Namen</th> <th>Številke proizvajalca</th> </tr> </thead> <tbody> <tr> <td>Vmesniški kabel sistema SMARTABLATE™</td> <td>Priklop terapevtskega katetra na generator SMARTABLATE™.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>		Ime kabla	Namen	Številke proizvajalca	Vmesniški kabel sistema SMARTABLATE™	Priklop terapevtskega katetra na generator SMARTABLATE™.
Ime kabla	Namen	Številke proizvajalca					
Vmesniški kabel sistema SMARTABLATE™	Priklop terapevtskega katetra na generator SMARTABLATE™.	D-1303-02-S D-1303-03-S					
Predvideni namen	Ta kabel omogoča priključitev elektrofiziološkega katetra, zunanje referenčne elektrode ali ovojnice Biosense Webster na ustrezno opremo. Kabel lahko znova uporabite ob upoštevanju omejitev čiščenja in sterilizacije v tem dokumentu.						
Razvrščanje	Razred Is (dodatek Annex VIII, pravilo Rule 1)						

**Slovenščina (Slovenian)**

**IZJAVA EU O SKLADNOSTI**

<b>Šifra GMDN</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Osnovna vrednost UDI-DI</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Ta izjava EU o skladnosti je izdana na lastno odgovornost proizvajalca.</b>	
Biosense Webster, Inc., izjavljamo, da je zgoraj naveden medicinski pripomoček v skladu z Uredbo o medicinskih pripomočkih (EU) 2017/745. Ta izjava je dana na podlagi: Certifikata EU o sistemu vodenja kakovosti št. 3828594CE01, ki ga je izdal zgoraj navedeni priglašeni organ v skladu z Dodatkom IX, Poglavjema I in III Uredbe o medicinskih pripomočkih (EU) 2017/745.	

Svenska (Swedish)							
EU-försäkran om överensstämmelse							
Tillverkarens namn	Biosense Webster, Inc.						
Tillverkarens adress	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
Auktoriserad representants namn och adress	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
Anmälda organets namn	DEKRA Certification B.V.						
Anmälda organets id-nummer	0344						
Tekniskt dokumentationsnummer	TD0022						
Produktnamn och handelsnamn	SMARTABLATE™ System Interface Cable						
Produktkod(er)/Produktsortiment och beskrivning	<table border="1"> <thead> <tr> <th>European Catalogue Number</th> <th>Manufacturing Part Number</th> </tr> </thead> <tbody> <tr> <td>D130302</td> <td>D-1303-02-S</td> </tr> <tr> <td>D130303</td> <td>D-1303-03-S</td> </tr> </tbody> </table>	European Catalogue Number	Manufacturing Part Number	D130302	D-1303-02-S	D130303	D-1303-03-S
	European Catalogue Number	Manufacturing Part Number					
D130302	D-1303-02-S						
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	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Kabelnamn</th> <th>Syfte</th> <th>Tillverkningsnummer</th> </tr> </thead> <tbody> <tr> <td>SMARTABLATE™-system gränssnittskabel</td> <td>Ansluter en terapeutisk kateter till en SMARTABLATE™-generator.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>	Kabelnamn	Syfte	Tillverkningsnummer	SMARTABLATE™-system gränssnittskabel	Ansluter en terapeutisk kateter till en SMARTABLATE™-generator.	D-1303-02-S D-1303-03-S
Kabelnamn	Syfte	Tillverkningsnummer					
SMARTABLATE™-system gränssnittskabel	Ansluter en terapeutisk kateter till en SMARTABLATE™-generator.	D-1303-02-S D-1303-03-S					
Avsett ändamål	Dessa kablar ger möjligheten att ansluta en Biosense Webster elektrofysiologikateter, en extern referenspatch eller hylsa till lämplig utrustning. Kablarna kan återanvändas förutsatt att rengörings- och steriliseringsbegränsningarna i detta dokument följs.						
Klassificering	Klass Is (bilaga Annex VIII, regel Rule 1)						
GMDN-kod	47487 – Electrical-only medical device connection cable, reusable						

**Svenska (Swedish)**

**EU-försäkran om överensstämmelse**

<b>Grundläggande UDI-DI-värde</b>	08468350a0003ET
<b>RoHS</b>	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.
<b>Denna EU-försäkran om överensstämmelse ges ut på tillverkarens ansvar.</b>	
Vi, Biosense Webster, Inc., intygar härmed att ovan nämnda medicintekniska produkt efterlever kraven i EU-förordningen om medicintekniska produkter 2017/745. Denna försäkran görs baserat på: EU:s kvalitetssystem, certifikatnummer 3828594CE01, utfärdat av anmält organ angivet ovan, i enlighet med bilaga IX, kapitel I och III i EU-förordningen om medicintekniska produkter 2017/745.	

<b>Türkçe (Turkish)</b>							
<b>AB UYGUNLUK BEYANI</b>							
<b>Üreticinin Adı</b>	Biosense Webster, Inc.						
<b>Üreticinin Adresi</b>	31 Technology Drive, Suite 200 Irvine, California 92618 USA						
<b>Yetkili Temsilcinin Adı ve Adresi</b>	Biosense Webster A division of Johnson & Johnson Medical NV/SA Leonardo Da Vincilaan 15 1831 Diegem, Belgium						
<b>Onaylanmış Kuruluşun Adı</b>	DEKRA Certification B.V.						
<b>Onaylanmış Kuruluşun Kimlik Numarası</b>	0344						
<b>Teknik Belge Numarası</b>	TD0022						
<b>Ürün ve Marka Ad(lar)ı</b>	SMARTABLATE™ System Interface Cable						
<b>Ürün Kodları/Ürün Çeşitliliği ve Açıklaması</b>	<table border="1"> <thead> <tr> <th>European Catalogue Number</th> <th>Manufacturing Part Number</th> </tr> </thead> <tbody> <tr> <td>D130302</td> <td>D-1303-02-S</td> </tr> <tr> <td>D130303</td> <td>D-1303-03-S</td> </tr> </tbody> </table>	European Catalogue Number	Manufacturing Part Number	D130302	D-1303-02-S	D130303	D-1303-03-S
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	<p>The Biosense Webster SMARTABLATE™ Cable is a Class I reusable, user sterilized device with no patient contact. The Cable is intended to be a bridge that interfaces with the SMARTABLATE™ System and Celsius™ catheter simultaneously. The Cable conveys electrical signals for electrograms, electrical energy for pacing, and RF energy for ablation between the system side and the Celsius™ catheter side. The Cable is provided to the customer sterilized in a package with a 3-year shelf life.</p> <table border="1"> <thead> <tr> <th>Kablo Adı</th> <th>Kullanım Amacı</th> <th>Üretim Numaraları</th> </tr> </thead> <tbody> <tr> <td>SMARTABLATE™ Sistem Arayüz Kablosu</td> <td>Teröpatik kateteri SMARTABLATE™ Jeneratörüne bağlar.</td> <td>D-1303-02-S D-1303-03-S</td> </tr> </tbody> </table>	Kablo Adı	Kullanım Amacı	Üretim Numaraları	SMARTABLATE™ Sistem Arayüz Kablosu	Teröpatik kateteri SMARTABLATE™ Jeneratörüne bağlar.	D-1303-02-S D-1303-03-S
Kablo Adı	Kullanım Amacı	Üretim Numaraları					
SMARTABLATE™ Sistem Arayüz Kablosu	Teröpatik kateteri SMARTABLATE™ Jeneratörüne bağlar.	D-1303-02-S D-1303-03-S					
<b>Hedeflenen Amaç</b>	Bu kablolar, bir Biosense Webster elektrofizyoloji kateterini, harici referans yamasını veya kılıfı uygun bir ekipmana bağlama imkanı sağlar. Kablolar, bu belgede verilen temizlik ve sterilizasyon kısıtlamalarına uyularak tekrar kullanılabilir.						
<b>Sınıflandırma</b>	Sınıf Is (Ek Annex VIII, Kural Rule 1)						

**Türkçe (Turkish)****AB UYGUNLUK BEYANI**

<b>GMDN Kodu</b>	47487 – Electrical-only medical device connection cable, reusable
<b>Temel UDI-DI değeri</b>	08468350a0003ET
<b>RoHS</b>	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.
<b><u>İşbu AB Uygunluk Beyanı, yalnızca Üreticinin sorumluluğu kapsamında verilir.</u></b>	
Biosense Webster, Inc. olarak yukarıda listelenen Tıbbi Cihazın (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 I ve III'e uygun olarak yukarıda belirtilen Onaylanmış Kuruluş tarafından verilen AB Kalite Sistemi Belge Numarası 3828594CE01	