DEKLARACJA ZGODNOŚCI

Prawny Wytwórca:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

Zakład produkcyjny:

Boston Scientific Corporation
2546 First Street, Propark,
El Coyol, Alajuela
Costa Rica

Przedstawiciel Europejski w UE:

Boston Scientific Limited
Ballybrit Business Park
Gallway
Irlandia

Produkt:

Produkty Tome/Autotome RX(patrz Załącznik A)
Dokumentacja Techniczna nr 90072940

Klasyfikacja:

Klasa IIa, Reguła 9 zgodnie z Załącznikiem IX Dyrektywy dotyczącej Wyrobów Medycznych

Deklarujemy, że produkty wymienione powyżej są zgodne ze wszystkimi odpowiednimi przepisami Dyrektywy Rady 93/42/EEC z dnia 14 czerwca 1993 dotyczącej Wyrobów Medycznych. Niniejsza deklaracja została wystawiona zgodnie z Załącznikiem II dyrektywy. Cała odnośna dokumentacja znajduje się pod kontrolą prawnego wytwórcy.

Jednostka Notyfikowana:

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Numer identyfikacyjny 2797

Numer Certyfikatu EN ISO 13485: 2016 MD 6700368
Numer Certyfikatu Aneks II.3: CE616288

Podpis, data wydania:

Nazwisko: Tony Carr
Stanowisko: Wice-Prezes ds. Zapewnienia Jakości
Podpis: /-/ *podpis nieczytelny* **Data:** 27 lutego 2020

Nazwisko: Jennifer Kimball
Stanowisko: Wice-Prezes ds. Rejestracji

Podpis: /-/ *podpis nieczytelny* **Data:** 27 lutego 2020

ZAŁĄCZNIK A

Tabela 1: Tome/Autotome RX Family

Ultratome Double Lumen Sphincterotome

UPN	GTIN	Device Description
M00530800	08714729163664	Ultratome™ Double Lumen Sphincterotome (5mm Short Nose - 20mm Cut Wire)
M00530810	08714729183143	Ultratome™ Double Lumen Sphincterotome (20mm Long Nose- 20mm Cut Wire)
M00530820	08714729193418	Ultratome™ Double Lumen Sphincterotome (5mm Short Nose - 30mm Cut Wire)
M00530830	08714729193425	Ultratome™ Double Lumen Sphincterotome (20mm Long Nose - 30mm Cut Wire)

Ultratome XL Triple Lumen Sphincterotome

UPN	GTIN	Device Description
M00535900	08714729103257	Ultratome™ XL Triple Lumen Sphincterotome (5mm Short Nose - 20mm Cut Wire)
M00535910	08714729103301	Ultratome™ XL Triple Lumen Sphincterotome (20mm Long Wire- 20mm Cut Wire)
M00535920	08714729103318	Ultratome™ XL Triple Lumen Sphincterotome (5mm Short Nose - 30mm Cut Wire)
M00535930	08714729103349	Ultratome™ XL Triple Lumen Sphincterotome (20mm Long Nose - 30mm Cut Wire)

MicroKnife XL Triple Lumen Needle Knife

UPN	GTIN	Device Description
M00532810	08714729172017	MicroKnife XL Triple Lumen Needle Knife

RX Needle Knife XL Triple Lumen Needle Knife

UPN	GTIN	Device Description
M00545840	08714729283799	RX Needle Knife XL Triple Lumen Needle Knife

Autotome RX Cannulating Sphincterotome

UPN	GTIN	Device Description
M00545150	08714729415138	Autotome™ RX 49 Cannulating Sphincterotome (20mm Cut Wire)
M00545160	08714729415152	Autotome™ RX 49 Cannulating Sphincterotome (30mm Cut Wire)
M00545170	08714729444749	Autotome™ RX 44 Cannulating Sphincterotome (20mm Cut Wire)

UPN	GTIN	Device Description
M00545180	08714729444756	Autotome™ RX 44 Cannulating Sphincterotome (30mm Cut Wire)
M00545190	08714729444763	Autotome™ RX 39 Cannulating Sphincterotome (20mm Cut Wire)
M00545200	08714729444770	Autotome™ RX 39 Cannulating Sphincterotome (30mm Cut Wire)

Jagtome RX Cannulating Sphincterotome

UPN	GTIN	Device Description	Components of Device	
			Autotome	Pre-loaded Guidewire
M00573500	08714729121169	Jagtome™ RX 49 Sphincterotome (20mm Cut Wire)	Autotome RX 49	Jagwire Stiff Shaft Guidewire (0.0.35" x 260cm)
M00573520	08714729121237	Jagtome™ RX 49 Sphincterotome (30mm Cut Wire)	Autotome RX 49	Jagwire Stiff Shaft Guidewire (0.035" x 260cm)
M00573540	08714729121251	Jagtome™ RX 44 Sphincterotome (20mm Cut Wire)	Autotome RX 44	Jagwire Stiff Shaft Guidewire (0.035" x 260cm)
M00573560	08714729719533	Jagtome™ RX 44 Sphincterotome (30mm Cut Wire)	Autotome RX 44	Jagwire Stiff Shaft Guidewire (0.035" x 260cm)
M00573580	08714729765301	Jagtome™ RX 39 Sphincterotome (20mm Cut Wire)	Autotome RX 39	Jagwire Stiff Shaft Guidewire (0.025" x 260cm)
M00573590	08714729765318	Jagtome™ RX 39 Sphincterotome (20mm Cut Wire)	Autotome RX 39	Jagwire Stiff Shaft Guidewire (0.025" x 450cm)
M00573600	08714729765325	Jagtome™ RX 39 Sphincterotome (30mm Cut Wire)	Autotome RX 39	Jagwire Stiff Shaft Guidewire (0.025" x 260cm)
M00573610	08714729776512	Jagtome™ RX 39 Sphincterotome (30mm Cut Wire)	Autotome RX 39	Jagwire Stiff Shaft Guidewire (0.025" x 450cm)
M00573000	08714729776710	Jagtome™ RX 49 Sphincterotome (20mm Cut Wire)	Autotome RX 49	Jagwire Extendable Guidewire (0.035" x 260cm)
M00573010	08714729776727	Jagtome™ RX 49 Sphincterotome (20mm Cut Wire)	Autotome RX 49	Jagwire Guidewire (0.035" x 450cm)
M00573020	08714729776734	Jagtome™ RX 49 Sphincterotome (30mm Cut Wire)	Autotome RX 49	Jagwire Extendable Guidewire (0.035" x 260cm)

UPN	GTIN	Device Description	Components of Device	
			Autotome	Pre-loaded Guidewire
M00573510	08714729121176	Jagtome™ RX 49 Sphincterotome (20mm Cut Wire)	Autotome RX 49	Jagwire Stiff Shaft Guidewire (0.035" x 450cm)
M00573530	08714729121244	Jagtome™ RX 49 Sphincterotome (30mm Cut Wire)	Autotome RX 49	Jagwire Stiff Shaft Guidewire (0.035" x 450cm)
M00573030	08714729776741	Jagtome™ RX 49 Sphincterotome (30mm Cut Wire)	Autotome RX 49	Jagwire Guidewire (0.035" x 450cm)
M00573040	08714729776659	Jagtome™ RX 44 Sphincterotome (20mm Cut Wire)	Autotome RX 44	Jagwire Extendable Guidewire (0.035" x 260cm)
M00573050	08714729776666	Jagtome™ RX 44 Sphincterotome (20mm Cut Wire)	Autotome RX 44	Jagwire Guidewire (0.035" x 450cm)
M00573060	08714729776673	Jagtome™ RX 44 Sphincterotome (30mm Cut Wire)	Autotome RX 44	Jagwire Extendable Guidewire (0.035" x 260cm)
M00573070	08714729776543	Jagtome™ RX 44 Sphincterotome (30mm Cut Wire)	Autotome RX 44	Jagwire Guidewire (0.035" x 450cm)
M00573550	08714729121268	Jagtome™ RX 44 Sphincterotome (20mm Cut Wire)	Autotome RX 44	Jagwire Stiff Shaft Guidewire (0.035" x 450cm)
M00573570	08714729121275	Jagtome™ RX 44 Sphincterotome (30mm Cut Wire)	Autotome RX 44	Jagwire Stiff Shaft Guidewire (0.035" x 450cm)
M00573080	08714729776642	Jagtome™ RX 39 Sphincterotome (20mm Cut Wire)	Autotome RX 39	Jagwire Stiff Shaft Guidewire (0.025" x 260cm)
M00573090	08714729776550	Jagtome™ RX 39 Sphincterotome (20mm Cut Wire)	Autotome RX 39	Jagwire Guidewire (0.025" x 450cm)
M00573100	08714729776536	Jagtome™ RX 39 Sphincterotome (30mm Cut Wire)	Autotome RX 39	Jagwire Stiff Shaft Guidewire (0.025" x 260cm)
M00573110	08714729776529	Jagtome™ RX 39 Sphincterotome (30mm Cut Wire)	Autotome RX 39	Jagwire Guidewire (0.025" x 450cm)

Hydratome RX Cannulating Sphincterotome

UPN	GTIN	Device Description	Components of Device	
			Autotome	Pre-loaded Guidewire
M00583000	08714729755159	Hydratome RX 49 Sphincterotome (20mm Cut Wire)	Autotome RX 49	Hydra Jagwire Guidewire (0.0.35" x 260cm)
M00583010	08714729755166	Hydratome RX 49 Sphincterotome (30mm Cut Wire)	Autotome RX 49	Hydra Jagwire Guidewire (0.0.35" x 260cm)
M00583020	08714729755173	Hydratome RX 49 Sphincterotome (20mm Cut Wire)	Autotome RX 49	Hydra Jagwire Guidewire (0.0.35" x 450cm)
M00583030	08714729755180	Hydratome RX 49 Sphincterotome (30mm Cut Wire)	Autotome RX 49	Hydra Jagwire Guidewire (0.0.35" x 450cm)
M00583040	08714729755197	Hydratome RX 44 Sphincterotome (20mm Cut Wire)	Autotome RX 44	Hydra Jagwire Guidewire (0.0.35" x 260cm)
M00583050	08714729755203	Hydratome RX 44 Sphincterotome (30mm Cut Wire)	Autotome RX 44	Hydra Jagwire Guidewire (0.0.35" x 260cm)
M00583060	08714729755210	Hydratome RX 44 Sphincterotome (20mm Cut Wire)	Autotome RX 44	Hydra Jagwire Guidewire (0.0.35" x 450cm)
M00583070	08714729755227	Hydratome RX 44 Sphincterotome (30mm Cut Wire)	Autotome RX 44	Hydra Jagwire Guidewire (0.0.35" x 450cm)

Stonetome Stone Removal Device

UPN	GTIN	Device Description
M00535110	08714729146599	Stonetome Stone Removal Device (20mm Long Nose, 20mm Cut Wire, Above Cut Wire)
M00535130	08714729146575	Stonetome Stone Removal Device (20mm Long Nose - 30mm Cut Wire, Above Cut Wire)
M00535150	08714729146667	Stonetome Stone Removal Device (5mm Short Nose - 20mm Cut Wire, Below Cut Wire)
M00535170	08714729146629	Stonetome Stone Removal Device (20mm Long Nose - 20mm Cut Wire, Below Cut Wire)
M00535190	08714729146612	Stonetome Stone Removal Device (5mm Short Nose- 30mm Cut Wire, Below Cut Wire)
M00535210	08714729146605	Stonetome Stone Removal Device

UPN	GTIN	Device Description
		(20mm Long Nose - 30mm Cut Wire, Below Cut Wire)

Dreamtome RX Sphincterotome

UPN	GTIN	Device Description	Components of Device	
			Autotome	Pre-loaded Guidewire
M00584000	08714729778226	Dreamtome RX 49 Sphincterotome (20mm cut wire)	Autotome RX 49	Dreamwire Guidewire (0.035" x 260cm)
M00584010	08714729778233	Dreamtome RX 49 Sphincterotome (30mm cut wire)	Autotome RX 49	Dreamwire Guidewire (0.035" x 260cm)
M00584020	08714729778240	Dreamtome RX 49 Sphincterotome (20mm cut wire)	Autotome RX 49	Dreamwire Guidewire (0.035" x 450cm)
M00584030	08714729778257	Dreamtome RX 49 Sphincterotome (30mm cut wire)	Autotome RX 49	Dreamwire Guidewire (0.035" x 450cm)
M00584040	08714729778264	Dreamtome RX 44 Sphincterotome (20mm cut wire)	Autotome RX 44	Dreamwire Guidewire (0.035" x 260cm)
M00584050	08714729778271	Dreamtome RX 44 Sphincterotome (30mm cut wire)	Autotome RX 44	Dreamwire Guidewire (0.035" x 260cm)
M00584060	08714729778288	Dreamtome RX 44 Sphincterotome (20mm cut wire)	Autotome RX 44	Dreamwire Guidewire (0.035" x 450cm)
M00584070	08714729778295	Dreamtome RX 44 Sphincterotome (30mm cut wire)	Autotome RX 44	Dreamwire Guidewire (0.035" x 450cm)

Table 2: List of UPN/ GTINs for Additional Products after Issuance of Original DoC

Jagtome Revolution RX Cannulating Sphincterotome

UPN	GTIN	Device Description	Pre-loaded Guidewire
M00584240	08714729953234	AutoTome RX 39, 20mm Cut Wire	260cm .025" Jagwire Revolution/ Straight
M00584250	08714729953241	AutoTome RX 39, 20mm Cut Wire	450cm .025" Jagwire Revolution/ Straight
M00584260	08714729953258	AutoTome RX 39, 30mm Cut Wire	260cm .025" Jagwire Revolution/ Straight
M00584270	08714729953265	AutoTome RX 39, 30mm Cut Wire	450cm .025" Jagwire Revolution/ Straight