

EC DECLARATION OF CONFORMITY

Legal Manufacturer: Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

Manufacturing Site(s): Boston Scientific Corporation
Two Scimed Place
Maple Grove, MN 55311
USA
(Monorail and Over-the-Wire)

Boston Scientific Medical Device
(Malaysia) SDN BHD
PMT 741, Persiaran Cassia Selatan 1,
Taman Perindustrian Batu Kawan,
14110 Bandar Cassia,
Pulau Pinang
Malaysia
(Monorail)

EU Authorized Representative: Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

Product: •Emerge™ MONORAIL™ PTCA Dilatation Catheter
•Emerge™ Push MONORAIL™ PTCA Dilatation Catheter
•Emerge™ OVER-THE-WIRE PTCA Dilatation Catheter
•Emerge™ Push OVER-THE-WIRE PTCA Dilatation Catheter

Design Dossier: 90670316
See Attachment A for Model Designations.

Classification: Class III, Rule 6 according to Annex IX of the MDD.

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First CE Marking Under DEKRA:

28 March 2012

Notified Body:

DEKRA Certification B.V.

Meander 1051

6825 MJ Arnhem

P.O. Box 5185

6802 ED Arnhem

THE NETHERLANDS

Identification Number: 0344

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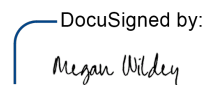
Certificates	
Certificate Name	Certificate Numbers
DEKRA Full Quality Assurance Certificate	3812454CE01
DEKRA EC Design-Examination Certificate	3812454DE23
DEKRA Management System Certificate - EN ISO 13485:2016 (Maple Grove)	3818536
BSI Management System Certificate – EN ISO 13485:2016 (Pulau Pinang)	MD 670368

All BSC SAP manufactured products are released per *Corp Form Product Shipment Release Requirements, 90213259*.

We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices as amended by Directive 2007/47/EC. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Signature, Date of Issue:

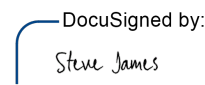
Name: Megan Wildey
Title: Director, Quality

Signature: 
 Signer Name: Megan Wildey
Signing Reason: I approve this document
Signing Time: 04 August 2021 | 5:28:42 PM EDT
D7F76F2EB42E4CD3897ED2DBD92BD5AA

04 August 2021

Date

Name: Steve James
Title: Director, Regulatory Affairs
Interventional Cardiology

Signature: 
 Signer Name: Steve James
Signing Reason: I approve this document
Signing Time: 04 August 2021 | 6:09:36 PM EDT
24B0FA69A1AF444BB09A9F657FF19A8B

04 August 2021

Date

ATTACHMENT A

Model Designation Summary

Emerge MONORAIL PTCA Dilatation Catheter

UPN	GTIN	Dimensions
H7493919308120	08714729799764	1.20 mm x 8 mm
H7493919308150	08714729799771	1.50 mm x 8 mm
H7493919308200	08714729799788	2.00 mm x 8 mm
H7493919308220	08714729799795	2.25 mm x 8 mm
H7493919308250	08714729799801	2.50 mm x 8 mm
H7493919308270	08714729799818	2.75 mm x 8 mm
H7493919308300	08714729799825	3.00 mm x 8 mm
H7493919308320	08714729799832	3.25 mm x 8 mm
H7493919308350	08714729799849	3.50 mm x 8 mm
H7493919308370	08714729799856	3.75 mm x 8 mm
H7493919308400	08714729799863	4.00 mm x 8 mm
H7493919312120	08714729799870	1.20 mm x 12 mm
H7493919312150	08714729799887	1.50 mm x 12 mm
H7493919312200	08714729799894	2.00 mm x 12 mm
H7493919312220	08714729799900	2.25 mm x 12 mm
H7493919312250	08714729799917	2.50 mm x 12 mm
H7493919312270	08714729799924	2.75 mm x 12 mm
H7493919312300	08714729799931	3.00 mm x 12 mm
H7493919312320	08714729799948	3.25 mm x 12 mm
H7493919312350	08714729799955	3.50 mm x 12 mm
H7493919312370	08714729799962	3.75 mm x 12 mm
H7493919312400	08714729799979	4.00 mm x 12 mm
H7493919315120	08714729799986	1.20 mm x 15 mm
H7493919315150	08714729799993	1.50 mm x 15 mm
H7493919315200	08714729800002	2.00 mm x 15 mm
H7493919315220	08714729800019	2.25 mm x 15 mm
H7493919315250	08714729800026	2.50 mm x 15 mm
H7493919315270	08714729800033	2.75 mm x 15 mm
H7493919315300	08714729800040	3.00 mm x 15 mm
H7493919315320	08714729800057	3.25 mm x 15 mm

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UPN	GTIN	Dimensions
H7493919315350	08714729800064	3.50 mm x 15 mm
H7493919315370	08714729800071	3.75 mm x 15 mm
H7493919315400	08714729800088	4.00 mm x 15 mm
H7493919320120	08714729800095	1.20 mm x 20 mm
H7493919320150	08714729800101	1.50 mm x 20 mm
H7493919320200	08714729800118	2.00 mm x 20 mm
H7493919320220	08714729800125	2.25 mm x 20 mm
H7493919320250	08714729800132	2.50 mm x 20 mm
H7493919320270	08714729800149	2.75 mm x 20 mm
H7493919320300	08714729800156	3.00 mm x 20 mm
H7493919320320	08714729800163	3.25 mm x 20 mm
H7493919320350	08714729800170	3.50 mm x 20 mm
H7493919320370	08714729800187	3.75 mm x 20 mm
H7493919320400	08714729800194	4.00 mm x 20 mm
H7493919330200	08714729800200	2.00 mm x 30 mm
H7493919330220	08714729800217	2.25 mm x 30 mm
H7493919330250	08714729800224	2.50 mm x 30 mm
H7493919330270	08714729800231	2.75 mm x 30 mm
H7493919330300	08714729800248	3.00 mm x 30 mm
H7493919330320	08714729800255	3.25 mm x 30 mm
H7493919330350	08714729800262	3.50 mm x 30 mm
H7493919330370	08714729800279	3.75 mm x 30 mm
H7493919330400	08714729800286	4.00 mm x 30 mm

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UPN	GTIN	Dimensions
H7493919408120	08714729799689	1.20 mm x 8 mm
H7493919408150	08714729799726	1.50 mm x 8 mm
H7493919412120	08714729799696	1.20 mm x 12 mm
H7493919412150	08714729799733	1.50 mm x 12 mm
H7493919415120	08714729799702	1.20 mm x 15 mm
H7493919415150	08714729799740	1.50 mm x 15 mm
H7493919420120	08714729799719	1.20 mm x 20 mm
H7493919420150	08714729799757	1.50 mm x 20 mm

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Emerge OVER-THE-WIRE PTCA Dilatation Catheter

UPN	GTIN	Dimensions
H7493919508120	08714729800378	1.20 mm x 8 mm
H7493919508150	08714729800385	1.50 mm x 8 mm
H7493919508200	08714729800392	2.00 mm x 8 mm
H7493919508220	08714729800408	2.25 mm x 8 mm
H7493919508250	08714729800415	2.50 mm x 8 mm
H7493919508270	08714729800422	2.75 mm x 8 mm
H7493919508300	08714729800439	3.00 mm x 8 mm
H7493919508320	08714729800446	3.25 mm x 8 mm
H7493919508350	08714729800453	3.50 mm x 8 mm
H7493919508370	08714729800460	3.75 mm x 8 mm
H7493919508400	08714729800477	4.00 mm x 8 mm
H7493919512120	08714729800484	1.20 mm x 12 mm
H7493919512150	08714729800491	1.50 mm x 12 mm
H7493919512200	08714729800507	2.00 mm x 12 mm
H7493919512220	08714729800514	2.25 mm x 12 mm
H7493919512250	08714729800521	2.50 mm x 12 mm
H7493919512270	08714729800538	2.75 mm x 12 mm
H7493919512300	08714729800545	3.00 mm x 12 mm
H7493919512320	08714729800552	3.25 mm x 12 mm
H7493919512350	08714729800569	3.50 mm x 12 mm
H7493919512370	08714729800576	3.75 mm x 12 mm
H7493919512400	08714729800583	4.00 mm x 12 mm
H7493919515120	08714729800590	1.20 mm x 15 mm
H7493919515150	08714729800606	1.50 mm x 15 mm
H7493919515200	08714729800613	2.00 mm x 15 mm
H7493919515220	08714729800620	2.25 mm x 15 mm
H7493919515250	08714729800637	2.50 mm x 15 mm
H7493919515270	08714729800644	2.75 mm x 15 mm
H7493919515300	08714729800651	3.00 mm x 15 mm
H7493919515320	08714729800668	3.25 mm x 15 mm
H7493919515350	08714729800675	3.50 mm x 15 mm
H7493919515370	08714729800682	3.75 mm x 15 mm
H7493919515400	08714729800699	4.00 mm x 15 mm
H7493919520120	08714729800705	1.20 mm x 20 mm

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UPN	GTIN	Dimensions
H7493919520150	08714729800712	1.50 mm x 20 mm
H7493919520200	08714729800729	2.00 mm x 20 mm
H7493919520220	08714729800736	2.25 mm x 20 mm
H7493919520250	08714729800743	2.50 mm x 20 mm
H7493919520270	08714729800750	2.75 mm x 20 mm
H7493919520300	08714729800767	3.00 mm x 20 mm
H7493919520320	08714729800774	3.25 mm x 20 mm
H7493919520350	08714729800781	3.50 mm x 20 mm
H7493919520370	08714729800798	3.75 mm x 20 mm
H7493919520400	08714729800804	4.00 mm x 20 mm
H7493919530200	08714729800811	2.00 mm x 30 mm
H7493919530220	08714729800828	2.25 mm x 30 mm
H7493919530250	08714729800835	2.50 mm x 30 mm
H7493919530270	08714729800842	2.75 mm x 30 mm
H7493919530300	08714729800859	3.00 mm x 30 mm
H7493919530320	08714729800866	3.25 mm x 30 mm
H7493919530350	08714729800873	3.50 mm x 30 mm
H7493919530370	08714729800880	3.75 mm x 30 mm
H7493919530400	08714729800897	4.00 mm x 30 mm

Emerge Push OVER-THE-WIRE PTCA Dilatation Catheter

UPN	GTIN	Dimensions
H7493919608120	08714729800293	1.20 mm x 8 mm
H7493919608150	08714729800330	1.50 mm x 8 mm
H7493919612120	08714729800309	1.20 mm x 12 mm
H7493919612150	08714729800347	1.50 mm x 12 mm
H7493919615120	08714729800316	1.20 mm x 15 mm
H7493919615150	08714729800354	1.50 mm x 15 mm
H7493919620120	08714729800323	1.20 mm x 20 mm
H7493919620150	08714729800361	1.50 mm x 20 mm

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