



Boston Scientific Corporation
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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

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

Product Name: Comet™ Pressure Guidewire
Comet™ II Pressure Guidewire
See Attachment A- Model Designation List

Design Dossier: 91038601

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

Notified Body: **DEKRA Certification B.V.**
Meander 1051
6825 MJ Arnhem
P.O. Box 5185
6802 ED Arnhem
The Netherlands
Identification Number: 0344

EC Certificates	
Certificate Name	Certificate Number
Annex II.3 (CE Marking of Conformity)	3812454CE01
Annex II.4 (EC Design Examination)	3812454DE39
EN ISO 13485:2016	3818536

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. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Name: Erin Farrens
Title: Director, Quality

Signature: 
 Signer Name: Erin Farrens
Signing Reason: I approve this document
Signing Time: 12 September 2022 | 5:34:39 PM EDT
E40B9FEBD2B04C7C816907CE223797D9

12 September 2022

Date

Name: Dan Krause
Title: Sr. Director, Regulatory Affairs

Signature: 
 Signer Name: Daniel Krause
Signing Reason: I approve this document
Signing Time: 12 September 2022 | 4:54:03 PM EDT
7ACA1B54D8BA4C13B98AEEC4A191BAFF

12 September 2022

Date

Attachment A- Model Designation List

Date of CE Marking: 10 February 2016

Table 1: List of UPN/GTINs on Original DoC

UPN	GTIN	Device Description
H7493932430	08714729904397	Comet™ Pressure Guidewire

Date of CE Marking: 24 March 2020

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

UPN	GTIN	Device Description
H74939359310	08714729960164	Comet™ II Pressure Guidewire