Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA USA 01752
508-683-4000

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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 2546 First Street, Propark El Coyol, Alajuela Costa Rica
EU Authorized Representative:	Boston Scientific Limited Ballybrit Business Park Galway Ireland
Product Name:	Resolution 360 ULTRA Clip **See Attachment A- Model Designation List**
Design Dossier/Technical File:	Technical File: 92539823
Product Classification:	Class IIb, Rule 5 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

Certificates	
Certificate Name	**Certificate Number**
Annex II.3 (Full Quality Assurance System)	3812454CE01
EN ISO 13485:2016	MD 670368

- All BSC SAP manufactured products are released per Global WI Semi-Automated Active Release, 90391555, using Global 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: Tony Carr
Title: **Multi-site Vice President, Quality Assurance**

Signature: T. Carr — 22 Sept 2020 **Date**

Name: Jennifer A. Kimball
Title: **Endoscopy Vice President, Regulatory Affairs**

Signature: Jennifer Kimball — September 22, 2020 **Date**

Attachment A- Model Designation List

Date of CE Marking: June 8, 2020

Table 1: List of UPN/ GTINs for Original DoC

UPN	**GTIN**	**Device Description**
M00521400	08714729997245	Resolution 360™ ULTRA Clip 235cm, Box of 1
M00521401	08714729997252	Resolution 360™ ULTRA Clip 235cm, Box of 10
M00521402	08714729997269	Resolution 360™ ULTRA Clip 235cm, Box of 20
M00521403	08714729997276	Resolution 360™ ULTRA Clip 235cm, Box of 40