

# CE - Declaration of Conformity



No.: 21 01 0482 A 004

We hereby declare that our products

Product:	Selectra	
Type:	Lead Implantation System:	see Attachment
EC-Class:	AIMD	

are in conformance with the Design Dossier Documentation according to Annex 3, Section 3 of the Directive 90/385/EEC (AIMD) for which the EC-Type Examination Certificate

Certificate No.:	13290GB419210128A	
Notified Body:	MEDCERT, Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH, Pilatuspool 2, 20355 Hamburg, Germany	
EEC No.:	0482	
Valid from:	January 28, 2021	

has been issued.

To these products our certified Full Quality Assurance System according to Annex 5, Section 3 and 4 of the Directive 90/385/EEC (AIMD) is applied. For this QA-system the certificate

Certificate No.:	I2 010275 0527 Rev. 00	
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany	
EEC No.:	0123	
Valid from:	March 3, 2020	

has been issued.

These products meet the provisions of the Directive 90/385/EEC (AIMD) which apply to them. Any subsequent revisions or renewed versions of the QA-certificate are applicable to this declaration. This declaration is made under the full and sole responsibility of the Manufacturer BIOTRONIK SE & Co. KG.

BIOTRONIK SE & Co. KG  
Woermannkehre 1  
12359 Berlin, Germany

January 29, 2021

i.V. Axel Steiof  
Director Regulatory Affairs



Attachment for  
 Declaration of Conformity No. 21 01 0482 A 004  
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**Product: Selectra Lead Implantation System**

Selectra IC - 50 - 59	Selectra IC - 50 - 69
Selectra IC - 90 - 59	Selectra IC - 90 - 69
Selectra Amplatz 6.0 - 45	Selectra Amplatz 6.0 - 55
Selectra BIO2 - 45	Selectra BIO2 - 55
Selectra Extended Hook - 45	Selectra Extended Hook - 55
Selectra Hook - 45	Selectra Hook - 55
Selectra MPEP - 45	Selectra MPEP - 55
Selectra Multipurpose Hook - 45	Selectra Multipurpose Hook - 55
Selectra Right - 45	Selectra Right - 55
Selectra Straight - 45	Selectra Straight - 55
Selectra 3D-40-32	Selectra 3D-55-32
Selectra 3D-65-32	Selectra 3D-40-39
Selectra 3D-55-39	Selectra 3D-65-39
Selectra 3D-40-42	Selectra 3D-55-42
Selectra 3D-65-42	
Selectra Accessory Kit	Selectra Slitter

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