

EC Type Examination Certificate

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the active implantable medical device(s) :

Selectra Lead Implantation System

with specifications listed in the appendix

of the manufacturer

BIOTRONIK SE & Co. KG
Woermannkehe 1
12359 Berlin
Germany

fulfills the below mentioned requirements of the **Council Directive 90/385/EEC**:

Annex 3

The certificate assumes that MEDCERT has to be informed of any significant change made to the approved product. Changes need further approval by MEDCERT.

For the placing on the market of active implantable medical devices covered by this certificate, a separate EC certificate of conformity according to Annex 4 or 5 of Council Directive 90/385/EEC is required.

Effective date: 2021-01-28

Expiry date: 2024-05-27

Report No.: 13290PS10F

Process No.: PP – 13290

Certificate No.: 13290GB419210128A

Hamburg, 2021-01-28



MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-188.15.03

Appendix of EC Type Examination Certificate

Process No.: PP – 13290

Certificate No.: 13290GB419210128A

Specifications**Selectra Lead Implantation System**

Selectra Amplatz 6.0-45	375 519
Selectra Amplatz 6.0-55	375 520
Selectra BIO2-45	375 523
Selectra BIO2-55	375 524
Selectra Extended Hook-45	375 527
Selectra Extended Hook-55	375 528
Selectra Hook-45	375 529
Selectra Hook-55	375 530
Selectra MPEP-45	375 531
Selectra MPEP -55	375 532
Selectra MPH-45	375 533
Selectra MPH-55	375 534
Selectra Right-45	375 535
Selectra Right-55	375 536
Selectra Straight-45	375 537
Selectra Straight-55	375 521
Selectra 3D-40-32	443 624
Selectra 3D-55-32	443 626
Selectra 3D-65-32	443 628
Selectra 3D-40-39	443 625
Selectra 3D-55-39	443 627
Selectra 3D-65-39	443 629
Selectra 3D-40-42	451 789
Selectra 3D-55-42	451 790
Selectra 3D-65-42	451 791
Selectra IC-50-59	393 289
Selectra IC-50-69	392 290
Selectra IC-90-59	392 291
Selectra IC-90-69	392 292
Selectra Accessory Kit	375 518
Selectra Slitter	383 119

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-188.15.03