ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 081711 0025 Rev. 00

Manufacturer:

Shanghai MicroPort EP MedTech Co., Ltd.
Building 23&28, Lane 588, Tianxiong Rd.
201318 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shanghai MicroPort EP MedTech Co., Ltd.
Building 23&28, Lane 588, Tianxiong Rd., 201318 Shanghai,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Cardiac RF Ablation Catheter,
Fixed Curve Diagnostic Catheter,
Steerable Curve Diagnostic Catheter,
Circular Mapping Catheter,
3D Irrigated Ablation Catheter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH18738EXT02

Valid from: 2018-11-19
Valid until: 2023-11-18

Date, 2018-11-07

Stefan Preiß

Digitally signed by Jighili Tatiana
Date: 2022.04.13 18:03:47 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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