



Certificate

No. Q5 081711 0018 Rev. 00

Holder of Certificate: **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

Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
Ablation Catheters, EP Diagnostic Catheters,
EP Navigation System and related accessories
(Cables, External Reference Patch),
Renal Artery RF Ablation Catheter,
Renal Artery RF Generator, Irrigation Pump,
Cardiac RF Generator, Tubing Set,
Cardiac Electrophysiology Stimulator,
Cable for Renal Artery RF Ablation Catheter**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1873807

Valid from: 2019-01-04

Valid until: 2019-09-17

Date, 2019-01-04

Stefan Preiß