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

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 027210 0023 Rev. 01

Manufacturer:

Suzhou Medical Appliance Factory
No. 18 Huatuo Rd., SSTT
215163 Suzhou New District
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Suzhou Medical Appliance Factory
No. 18 Huatuo Rd., SSTT, 215163 Suzhou New District,
PEOPLE'S REPUBLIC OF CHINA

Suzhou Huatuo Medical Instruments Co., Ltd.
36, Yongfang Road, Huangqiao Town, 215132 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Nerve and Muscle Stimulators

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

Report No.: SH1900101

Valid from: 2019-10-28
Valid until: 2024-05-26

Date, 2019-10-28

Stefan Preiß
Head of Certification/Notified Body

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

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