ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 11 01883 002

Manufacturer:

SHENZHEN KENTRO MEDICAL ELECTRONICS CO., LTD.
No.3, Xihu industry zone
Xikeng Village, Henggang Town
Longgang District
518115 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Wellkang Ltd
Suite B, 29 Harley Street
LONDON
W1G 9QR
UNITED KINGDOM

Product Category(ies):

Transcutaneous Electrical Nerve Stimulator

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.: GZ1731301

Valid from: 2018-05-07
Valid until: 2023-05-06

Date, 2018-05-07

Stefan Preiß

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

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Facility(ies):

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Longgang District, 518115 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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