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

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 002145 0001 Rev. 01

Manufacturer:

Shenzhen IMDK Medical Technology CO., Ltd
C Zone,10F, Building 16
Yuanshan Industrial B Area
Gongming Street
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Pulse Oximeter, Ultrasonic Doppler Fetal Heart Rate Detector, Portable Mesh Nebulizer

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.: GZ2028301

Valid from: 2021-04-29
Valid until: 2023-09-24

Date, 2021-04-29

Christoph Dicks
Head of Certification/Notified Body

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

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