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

TÜV SÜD
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. 00

Manufacturer:

[redacted]
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

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 and Ultrasonic Doppler Fetal Heart Rate Detector

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.: GZ1828301

Valid from: 2018-09-25
Valid until: 2023-09-24

Date, 2018-09-25

Stefan Preiß

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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