



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zig.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. 00

**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

**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