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

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 085300 0008 Rev. 01

Manufacturer:

Hunan Accurate Bio-Medical Technology Co., Ltd.
6th Floor, Biyang Industrial Zone
Lijiacun Road
Xueshi Street of Yuelu District
410208 Changsha, Hunan Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Hunan Accurate Bio-Medical Technology Co., Ltd.
6th Floor, Biyang Industrial Zone, Lijiacun Road, Xueshi Street of Yuelu District, 410208 Changsha, Hunan Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Pulse Oximeters, Spo2 Sensors and Fetal Doppler

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.: GZ1810201

Valid from: 2019-05-15
Valid until: 2023-10-09

Date, 2019-05-15

Stefan Preiß

Digitally signed by Vidiborschii Vladimir
Date: 2021.03.05 18:12:08 EET
Reason: MoldSign Signature
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