

Product certificate



Beauftragt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
für Arzneimittel und
Medizinprodukte
ZLG-BS-244.10.08

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding
(Devices in Class IIa, IIb or III)

No. G1 092582 0009 Rev. 00

Manufacturer: Xuzhou Yongkang Electronic Science Technology Co., Ltd.
4F Building C8, 40 Jingshan Road
Economic and Technological Development Zone,
221000 Xuzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Xuzhou Yongkang Electronic Science Technology Co., Ltd.
4F Building C8, 40 Jingshan Road
Economic and Technological Development Zone,
221000 Xuzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Vital Signs Monitor,
Handheld Pulse Oximeter,
Fingertip Pulse Oximeter,
Multiparameter Patient Monitor

The Certification Body of TÜV SÜD Product Service GmbH declares that the manufacturer has implemented a quality assurance system for design and production inspection of the respective devices / device categories in accordance with the requirements of this Directive and the surveillance system conforms to the requirements of this Directive and Annex II. For marketing of class III devices an additional Annex II also notes overleaf.

Report No.: SH1966201

Valid from: 2019-11-26
Valid until: 2024-05-26



Date, 2019-11-26

C. Dicks
Christoph Dicks
Head of Certification

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0112
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Deutsche
Akkreditierungsstelle
D-ZM 11321-01-00

Product Service

Certificate

No. Q5 092582 0008 Rev. 00

Holder of Certificate: Xuzhou Yongkang Electronic Science Technology Co., Ltd.
4F Building C8, 40 Jingshan Road
Economic and Technological Development Zone
221000 Xuzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Xuzhou Yongkang Electronic Science Technology Co., Ltd.
4F Building C8, 40 Jingshan Road, Economic and Technological Development Zone,
221000 Xuzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark: 

Scope of Certificate: Design and Development, Production and Distribution of Vital Signs Monitor, Handheld Pulse Oximeter, Fingertip Pulse Oximeter, Multiparameter Patient Monitor, Production and Distribution of Wrist Type Blood Pressure Monitor, Infrared Thermometer, Arm Type Blood Pressure Monitor, Fetal Doppler

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1886204
Valid from: 2019-04-30
Valid until: 2022-04-29

S. Preiß
Stefan Preiß

Date, 2019-04-30

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