ZLG-85-244.10.08

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 092582 0010 Rev. 00

Manufacturer: Xuzhou Yongkang E
Technology Co., Ltd
4F Building C8, 40 Jingshan R
Economic and Technological D
221000 Xuzhou
PEOPLE'S REPUBLIC OF CH

Facility(ies): Xuzhou Yongkang Electronic
4F Building C8, 40 Jingshan R
Development Zone, 221000 X
CHINA

Product Category(ies): Wrist Type Blood Pr
Infrared Thermomet
Arm Type Blood Pre
Fetal Doppler

The Certification Body of TÜV SÜD Product Service GmbH declar
manufacturer has implemented a quality assurance system for mu
respective devices / device categories in accordance with MDD A
system conforms to the requirements of this Directive and is subje
marketing of class IIb and III devices an additional Annex III certifi
overleaf.

Report No.: SH1966201

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

Date, 2019-11-26

Christoph Dicks
Head of Certifica

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TÜV SÜD Product Service GmbH is Notified Body with identificati

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CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認證證書 ◆ ZERTIFIKAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

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.: SH1866204
Valid from: 2019-04-30
Valid until: 2022-04-29

Date, 2019-04-30

Stefan Preiß

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TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認證證書 ◆ CERTIFICAT

CE ISO