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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 005136 0001 Rev. 01

Holder of Certificate: **Shenzhen Witleaf Medical Electronics Co., Ltd.**
13/F-B2, Block 1
Senyang Science Park
No.7 Road, West District of High-Tech Park
Guangming District
518132 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Patient Monitor, Rapid Intervention Capnograph, Fingertip Pulse Oximeter, Handheld Pulse Oximeter**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 005136 0001 Rev. 01

Report No.: GZ2035701

Valid from: 2021-04-16
Valid until: 2022-04-14

Date, 2021-04-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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D-ZM-11321-01-00

TÜV SÜD
Product Service

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No. Q5 005136 0001 Rev. 01

Applied Standard(s):

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

Facility(ies):

Shenzhen Witleaf Medical Electronics Co., Ltd.
13/F-B2, Block 1, Senyang Science Park, No.7 Road, West District of High-Tech Park, Guangming District, 518132 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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