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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 003960 0002 Rev. 02

Manufacturer:

Better Life Medical Technology Co., Ltd.
Room 201, Building 6, No.188 Fuchunjiang Road
Suzhou High-Tech District
215153 Suzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Defibrillator Monitor,**
Patient Monitor

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. 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:G1 003960 0002 Rev. 02

Report No.: SH20114301

Valid from: 2021-03-03
Valid until: 2023-10-28

Date, 2021-03-03

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Trocin Caterina
Date: 2021.09.02 21:31:29 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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

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

TÜV SÜD Product Service

Certificate

No. Q5 003960 0001 Rev. 02

Holder of Certificate:

Better Life Medical Technology Co., Ltd.
Room 201, Building 6, No.188 Fuchunjiang Road
Suzhou High-Tech District
215153 Suzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Better Life Medical Technology Co., Ltd.
Room 201, Building 6, No.188 Fuchunjiang Road, Suzhou High-Tech District, 215153 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

See scope of certificate

Certification Mark:

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

Scope of Certificate:

**Design and Development,
Production Service and Distribution of
Defibrillator Monitor,
Patient Monitor,
Central Monitoring Software**

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). 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 003960 0001 Rev. 02

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