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

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: 2022.06.17 17:33:09 GMT+03:00
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

TÜV®

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

TÜV SÜD
Product Service

Certificate

No. Q5 003960 0001 Rev. 03

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. 03

Report No.: SH21114301

Valid from: 2021-10-29
Valid until: 2024-10-28

Date, 2021-09-10

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

betterlife

Making life better
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Declaration of Conformity

Manufacturer: **Better Life Medical Technology Co., Ltd**
Room 201, Bldg.6, No.188 Fuchunjiang Rd, Suzhou High-tech District, Suzhou, 215153, Jiangsu Province, China

European Representative: **Wellkang Ltd**
Enterprise Hub， NW Business Complex，
1 Beraghmore Road, Derry， BT48 8SE， Northern Ireland, UK.

Product Name:	**Patient Monitor**
Model Number:	**Vitavue 10、Vitavue 12、Vitavue 15**
UMDNS/GMDN Code:	**33586**
Classification (MDD, Annex IX):	**IIb, rule 10**
Conformity Assessment Route:	**Annex II.3**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC

Notified Body:	**TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany**
Identification number:	**CE0123**
(EC) Certificate(s):	**No. G1 003960 0002 Rev.02**
Expire date of the Certificate:	**2023-10-28**
Start of CE Marking:	**2019-11-7**
Place, Date of Issue:	**Suzhou, 2021/05/17**

Signature: James Lu

Name: James Lu

Position: Management Representative