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Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
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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:G10039600002Rev.02

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Christoph Dicks
Head of Certification/Notified Body