



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
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 095178 0008 Rev. 00

Manufacturer:

Baisheng Medical Co.,Ltd.

No.11 Fusheng Road, Xinhui District
529100 Jiangmen City, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Baisheng Medical Co.,Ltd.

No.11 Fusheng Road, Xinhui District, 529100 Jiangmen City,
Guangdong, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Disposable Retrieval Bag, Disposable Suction Irrigation Set,
Disposable Trocar, Disposable Veress Needle, Defibrillation
Electrode**

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. See also notes overleaf.

Report No.:

GZ1925404

Valid from:

2020-01-22

Valid until:

2024-03-31

Date,

2020-01-22

Christoph Dicks

Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆



Certificate

No. Q5 095178 0009 Rev. 01

Holder of Certificate: **Baisheng Medical Co.,Ltd.**
No.11 Fusheng Road, Xinhui District
529100 Jiangmen City, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Electrosurgical Generators and Accessories, Electrosurgical Pencils, Neutral Electrodes, Electrosurgical Electrodes, Electrosurgical Forceps and Cables, Disposable ECG Electrodes, Disposable Skin Staplers, Staple Removers, Disposable Retrieval Bags, Disposable Suction Irrigation Sets, Disposable Trocars, Disposable Veress Needles, **Defibrillation Electrodes** and Disposable Medical Face Mask

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.: GZ2025401

Valid from: 2021-03-18

Valid until: 2022-11-07

Date, 2021-03-18

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 095178 0009 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): Baisheng Medical Co.,Ltd.
No.11 Fusheng Road, Xinhui District, 529100 Jiangmen City,
Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of
Electrosurgical Generators and Accessories, Electrosurgical
Pencils, Neutral Electrodes, Electrosurgical Electrodes,
Electrosurgical Forceps and Cables, Disposable ECG Electrodes,
Disposable Skin Staplers, Staple Removers, Disposable Retrieval
Bags, Disposable Suction Irrigation
Sets, Disposable Trocars, Disposable Veress Needles,
Defibrillation Electrodes and Disposable Medical Face Mask