

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets, Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009
Effective date: 2020-11-18
Expiry date: 2024-05-26
Issue date: 2020-11-18


Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



Certificate

No. Q6 003096 0003 Rev. 01

Holder of Certificate: **Guangzhou iCare
Medical Technology Co., Ltd.**
First floor A No.8
Lianhua Port Industrial Zone
Lotus Mountain Bonded Area, Shilou Town
Panyu District
511440 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of
Insulin pen needles, Safety Lancets,
Disposable Insulin Syringes (with Needle),
Alcohol Pads**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), 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:Q6 003096 0003 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q6_003096_0003_Rev.01)

Report No.: SH21124101

Valid from: 2021-08-27

Valid until: 2024-06-28

Date, 2021-08-27



Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q6 003096 0003 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):

Guangzhou iCare Medical Technology Co., Ltd.
First floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain
Bonded Area, Shilou Town, Panyu District, 511440 Guangzhou,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate