



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

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 080338 0015 Rev. 00**

## Manufacturer

**Jiangsu JianYu**

**Health Medical Co., Ltd.**

Zhixi Town Industry Zone

213251 Jintan City, Jiangsu Province

PEOPLE'S REPUBLIC OF CHINA

## EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, GERMANY

## Product

### Category(ies):

**Gauze Swab, Ear Ulcer Syringe,  
Sponge Sticker, Gas Mask Head Strap,  
Medical Oral Swab, Clean Connecting  
Tube, Towel Clip, Bit Mat, Medicine Bowl,  
Surgical Needles Collection Box, Brush-Sponge,  
Specimen Container, First Aid Kits,  
Catheterization Pack, Basic Dressing Pack,  
Oral Hygiene Pack, Umbilical Cord Clamp,  
Surgical Gown, Surgical Drape, Isolation Gown,  
Patient Stabilizer, Feeding Bag,  
Enteral Drainage Bag,  
Foreskin Cutting Fixture,  
Sterile Gauze Bandage,  
Sterile Face Mask for Medical Use**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:**

SH1871508

**Valid from:**

2018-12-14

**Valid until:**

2022-10-23

**Date,**

2018-12-14

Stefan Preiß



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**Facility(ies):**

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Zhixi Town Industry Zone, 213251 Jintan City,  
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA