



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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 059454 0026 Rev. 01**

## Manufacturer

**Dansu-China Health Care Co., Ltd.**

No. 366, Pengjialing  
Yongfeng Street  
Hanyang District  
430050 Wuhan  
PEOPLE'S REPUBLIC OF CHINA

## Product Category(ies):

**Sterile Medical Applicators, Sterile Non-woven Swabs,  
Sterile Disposable Dressing Packs  
and Procedure Packs, Sterile Gauze Swabs,  
Sterile Gauze Balls, Sterile Medical Bandage,  
Sterile Medical Gloves, Sterile Tongue Depressors,  
Sterile Drape / Surgical Drapes,  
Surgical Packs / Kit,  
Disposable Medical Bedsheets, Surgical Gown,  
First Aid Kit, Disposable Medical Basin,  
Disposable Medical Tray,  
Disposable Medical Forceps,  
Dialysis Kit/Haemodialysis Fistula ON/OFF Kit,  
Baby Delivery Kit, Catheterization Pack/Catheter Pack,  
Male Circumcision Kit, Suture Removal Kit,  
Suture Kit, Tracheostomy Pack,  
Umbilical Catheter Tray Kit, Chest Tube Tray Kit,  
PICC Catheter Insertion Dressing Care Kit,  
Foam Swabstick, Adhesive Fixation Clip**

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. 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:G2S 059454 0026 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G2S 059454 0026 Rev. 01)

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**Date,** 2021-02-04

Christoph Dicks  
Head of Certification/Notified Body