



EC Certificate

Production Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 059454 0028 Rev. 01

Manufacturer: Dansu-China Health Care Co., Ltd.

> No. 366, Pengjialing Yongfeng Street Hanyang District 430050 Wuhan

PEOPLE'S REPUBLIC OF CHINA

Product Gauze Swabs with X-ray Detectable Thread, Category(ies):

Gauze Balls With X-ray Detectable Thread.

Sterile Disposable Dressing Packs and Procedure Packs, Scissors,

Dissecting & Tissue Forceps,

Haemostatic Forceps, Needle Holders,

Retractors, Curets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III 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:G2 059454 0028 Rev. 01

Report No.: SH2043602

Valid from: 2021-02-04 Valid until: 2024-05-26

Date. 2021-02-04

Christoph Dicks

Head of Certification/Notified Body