



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 18 01 65303 013

Manufacturer: **Sword Xiantao Disposable Protective Products Factory**

Liukou Industrial Zone
433000 Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA



EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): Non Woven Cap, Non Woven Face Mask, Surgical Gown, Coverall, Non Woven Shoe Cover, Surgical Drape, Isolation Gown, Oversleeves, Disposable Examination Gloves, Wooden Tongue Depressor, Wooden Vaginal Spatula, Cotton Tip, Under Pad, Beard Cover, Surgical Kit, Protection Coat, Apron, Neck Paper, Dental Bib, Dental Kit, First-aid Kit (Case) , Patient Kit

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.: SH18298EXT01

Valid from: 2018-03-20
Valid until: 2023-03-19



S. Preiß

Date, 2018-02-23

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

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Factory**

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Province, PEOPLE'S REPUBLIC OF CHINA**