



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



**Date,** 2018-02-23

*Stefan Preiß*  
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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