



# 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 109384 0004 Rev. 00**

## Manufacturer

### Xuchang Zhengde Environstar Medical Products Co., Ltd.

Area B, Baihua Road East  
South Side of Erji river  
Industry Cluster District  
Yanling County  
461200 Xuchang, Henan  
PEOPLE'S REPUBLIC OF CHINA

## Product Category(ies):

**Sterile Drapes,  
Sterile Surgical Gowns,  
Protective Coverall,  
Equipment Cover,  
Surgical Packs**

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 109384 0004 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G2S_109384_0004_Rev.00)

**Report No.:** SH2055402

**Valid from:** 2020-10-27

**Valid until:** 2024-05-26

**Date,** 2020-10-27

Christoph Dicks  
Head of Certification/Notified Body