



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 005447 0002 Rev. 00**

**Manufacturer**

**Changzhou HolyMED  
Products Co., Ltd**

**Facility(ies):**

525 Changwu Road South Wujin District,  
Changzhou City, 213167, China

**Product  
Category(ies):**

**Sterile Surgical Gowns,  
Sterile Surgical Drapes,  
Sterile 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. See also notes overleaf.

**Report No.:**

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**Valid until:**

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**Date,** 2018-10-30

Stefan Preiß