



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-244.10.08



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 104197 0003 Rev. 00**

### Manufacturer

**Henan Gore Medical Instruments Co., Ltd.**

The North Industrial Area of Ding Luan  
453412 Changyuan County, Henan  
PEOPLE'S REPUBLIC OF CHINA

### Product Category(ies):

**Disposable Medical Mask,  
Disposable Medical Cap,  
Medical Absorbent Gauze Patches,  
Medical Cotton Swab,  
Disposable Medical Bedsheet,  
Disposable Surgical Gown**

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.:** SH19149901

**Valid from:** 2020-03-11  
**Valid until:** 2024-05-26

**Date,** 2020-03-11

Christoph Dicks  
Head of Certification/Notified Body

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