



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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. [REDACTED]

Manufacturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

**Product
Category(ies):**

**Gauze Sponge without X-ray,
Gauze Ball without X-ray,
Non-woven sponge, Non-woven face mask,
Surgical gown, Isolation gown/ Coverall,
Disposable underpad, Alcohol pad, Surgical Drape,
Disposable Examination Gloves,
Wooden Tongue Depressor**

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.:

[REDACTED]

Valid from:

2019-10-28

Valid until:

2021-07-06

Date, 2019-10-28

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



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No. [REDACTED]

Facility(ies): [REDACTED] PEOPLE'S
 REPUBLIC OF CHINA

海安美佳医用敷料有限公司
 及供閱覽复印无效

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

