



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 094018 0009 Rev. 01

Manufacturer

**YUHUAN CITY SHENGBO MOULD
MANUFACTURING CO., LTD.**
WESTERN OF CHINESE STERILE
MEDICAL EQUIPMENT BASE, QINGGANG TOWN
317606 YUHUAN CITY, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Gynecological set,
Disposable vaginal speculum,
Disposable cervical brush and spatula,
Anoscope**

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 094018 0009 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G2S_094018_0009_Rev_01)

Report No.: SH211008EXT01

Valid from: 2021-02-02

Valid until: 2024-05-26

Date, 2021-02-02

Christoph Dicks
Head of Certification/Notified Body



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 IIa, IIb or III)

No. G2 094018 0010 Rev. 00

Manufacturer: **YUHUAN CITY SHENGBO MOULD
 MANUFACTURING CO., LTD.**
 WESTERN OF CHINESE STERILE
 MEDICAL EQUIPMENT BASE, QINGGANG TOWN
 317606 YUHUAN CITY, ZHEJIANG PROVINCE
 PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Disposable oxygen mask,
 Disposable nebulizer oxygen mask**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. 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:G2_094018_0010_Rev.00

Report No.: SH211008EXT01

Valid from: 2021-02-02
Valid until: 2024-05-26

Date, 2021-02-02

Christoph Dicks
 Head of Certification/Notified Body

TÜV SÜD
 CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ СЕРТИФИКАТ ◆ 證書 ◆ 認證書 ◆ CERTIFICATE ◆ CERTIFICATE ◆ CERTIFICATE