



Certificate

No. Q6 094018 0008 Rev. 01

Holder of Certificate: 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

Facility(ies): 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

Certification Mark:



Scope of Certificate: Production and Distribution of

Gynecological set,

Disposable vaginal speculum,

Disposable cervical brush and spatula,

Disposable oxygen mask,

Disposable nebulizer oxygen mask,

Ear speculum, Nasal speculum,

Tongue depressor, Urine cup, Anoscope

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

SH18100805

Valid from: Valid until:

2019-03-15 2022-03-14

Date.

2019-03-05

Stefan Preiß

1. Punil

