



## **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 Disposable oxygen mask,

Category(ies): 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: <a href="https://www.tuvsud.com/ps-cert?q=cert:G2.094018.0010.Rev..00">www.tuvsud.com/ps-cert?q=cert:G2.094018.0010.Rev..00</a>

Report No.: SH211008EXT01

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

Date, 2021-02-02

Christoph Dicks

Head of Certification/Notified Body