



Certificate

No. Q5 087066 0010 Rev. 03

Holder of Certificate: **FITONE LATEX
PRODUCTS CO., LTD. GUANGDONG**

No. 5 Tongyi Road
Lingbei Industrial Zone, Suixi
524338 Zhanjiang, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
Natural Rubber Latex Male Condoms,
Single-use Sterile Latex Surgical Gloves,
Single-use Medical Latex Examination Gloves,
and Natural Latex Rubber Probe Covers.
Production and Distribution of
Medical Face Masks, and
Medical Nitrile Examination Gloves.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 087066 0010 Rev. 03

Report No.: SH2186702

Valid from: 2022-01-19

Valid until: 2023-03-11

Date, 2022-01-19

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

FITONE LATEX PRODUCTS CO., LTD. GUANGDONG
No. 5 Tongyi Road, Lingbei Industrial Zone, Suixi, 524338
Zhanjiang, Guangdong, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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