DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

# Certificate

## Q5 087066 0010 Rev. 01

**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

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

**Certification Mark:**

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

**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, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH2086701

**Valid from:** 2020-04-17
**Valid until:** 2023-03-11

Digitally signed by Guțan Ghenadie
Date: 2021.12.23 12:49:42 EET
Reason: MoldSign Signature
Location: Moldova

**Date,** 2020-04-17

Christoph Dicks
Head of Certification/Notified Body

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

A4 / 07.17


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