

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT ◆ TÜV SÜD



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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 087066 0011 Rev. 00

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

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): Natural Rubber Latex Male Condoms

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1886707

Valid from: 2019-04-30

Valid until: 2024-03-11

Date, 2019-04-30

Stefan Preiß

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Facility(ies):

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524338 Zhanjiang, Guangdong, PEOPLE'S
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