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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 087066 0008 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

Facility(ies):

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

Product Category(ies):

Single-use Sterile Latex Surgical Gloves

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. See also notes overleaf.

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Date, 2019-01-28

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123