ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 14 07 31712 018

Manufacturer:
Shanghai Motex Healthcare Co., Ltd.
No.369 Jiasong Zhong Road,Huaxin Town
Qingpu
201708 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Motex Healthcare Europe
23, rue de Rotterdam
4000 Liege
BELGIUM

Product Category(ies):
Sterile 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.

Report No.: SH14004EXT01

Valid from: 2014-11-03
Valid until: 2019-11-02

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Date, 2014-08-20

Hans-Heiner Junker

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

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Facility(ies):

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No.369 Jiasong Zhong Road,Huaxin Town, Qingpu,
201708 Shanghai, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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