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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 061155 0014 Rev. 02

Manufacturer: **TERANG NUSA (MALAYSIA) SDN. BHD.**
2, Jalan 8, Pengkalan Chepa 2, Industrial Zone
16100 Kota Bharu, Kelantan
MALAYSIA

Product Category(ies): **Sterile Surgical Gloves**
Sterile Radiation Reducing Surgical Gloves

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. 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:G1 061155 0014 Rev. 02

Report No.: MYQMH0720061-721425944

Valid from: 2021-02-19
Valid until: 2024-05-26

Date, 2021-02-19

Christoph Dicks
Head of Certification/Notified Body

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

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