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

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 055809 0022 Rev. 03

Manufacturer:

Gentec (Shanghai) Corporation
No. 499 Wenji Road
Songjiang District
201616 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Terminal Units for Compressed Medical Gases of Medical Gas Pipe System,
Medical Suction Equipment (Powered from Vacuum),
Medical Flow Meter for Terminal units of Medical Gas Pipe System,
Medical Gas Pressure Regulators,
Medical Gas Pressure Regulators with Flow Metering Devices, Low Pressure Hose Assemblies for Use with Medical Gases, Breathing Circuits, Face Masks, Suction Kits
Terminal Units for Anaesthetic Gas Scavenging Systems,
Respiratory Tract Humidifiers for Medical Use,
Medical Air/Oxygen Blender,
Nebucare In-line Nebulizer,
Portable Mesh-Sonic Nebulizer, Nebulizer Kit,
Humidification Chamber,
High FLow Nasal Cannula

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 055809 0022 Rev. 03

Report No.: SH20387EXT01
Valid from: 2021-04-01
Valid until: 2024-05-26
Date, 2021-04-01

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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