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

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 17 02 55809 019

Manufacturer:

Gentec (Shanghai) Corporation
No.1988 Yushu Road
Songjiang District
201699 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

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

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.: SH17387EXT01

Valid from: 2017-05-15
Valid until: 2022-05-14

Date, 2017-02-21

Stefan Preiß

04052768704252

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

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Facility(ies):

Gentec (Shanghai) Corporation
No.1988 Yushu Road, Songjiang District, 201699
Shanghai, PEOPLE'S REPUBLIC OF CHINA

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

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