



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 101591 0002 Rev. 00

Manufacturer:

Vitaltec Corporation

No. 12, Lane 4-30, Chyuan-Zhou Rd.
Hou-Li Dist.
42142 Taichung City
TAIWAN

**Product Category(ies): Sterile Respiratory Care Products including
Closed Suction Systems and Tracheostomy
Tubes**

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.:

TW1804801

Valid from:

2019-08-14

Valid until:

2024-05-26

Date,

2019-08-14

Stefan Preiß

Head of Certification/Notified Body



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Facility(ies):

Vitaltec Corporation

No. 12, Lane 4-30, Chyuan-Zhou Rd., Hou-Li Dist., 42142

Taichung City, TAIWAN