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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 044963 0035 Rev. 01

Manufacturer:

Fazzini s.r.l.
SS Padana Superiore 317
20090 Vimodrone (MI)
ITALY

Product Category(ies):

Suction pumps, Powered nebulisers, diaphragm, piston and ultrasonic, Rebreathing bags and anesthesia masks, Reanimation bags and face masks, Nasal cannula and connecting tubes for oxygen and aerosol therapy

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. 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:G2 044963 0035 Rev. 01

Report No.: ITA1466063

Valid from: 2021-03-29
Valid until: 2024-05-26

Date, 2021-03-29

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Belan Irina
Date: 2021.07.08 15:47:49 EEST
Reason: MoldSign Signature
Location: Moldova

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

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