



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-244.10.08



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](http://www.tuvsud.com/ps-cert?q=cert:G2_044963_0035_Rev_01)

**Report No.:**

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**Valid from:**

2021-03-29

**Valid until:**

2024-05-26

**Date,**

2021-03-29

Christoph Dicks  
Head of Certification/Notified Body