



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
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 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 070143 0004 Rev. 00**

**Manufacturer:** **SAN-O-SUB Italia S.r.l.**  
 Via L. da Vinci, 168  
 20090 Trezzano sul Naviglio (MI)  
 ITALY

**Facility(ies):** SAN-O-SUB Italia S.r.l.  
 Via L. da Vinci, 168, 20090 Trezzano sul Naviglio (MI), ITALY

**Product Category(ies):** **Pressure regulators,  
 pressure regulators with integrated  
 cylinder valves,  
 flowmeters, humidifiers  
 for medical gases**

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.:** ITA1277216

**Valid from:** 2019-09-16

**Valid until:** 2024-05-26

**Date,** 2019-07-10

Stefan Preiß  
 Head of Certification/Notified Body

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