



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