ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 14 06 70143 003

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 regulator,
pressure regulators with integrated cylinder valves,
flowmeters, humidifier
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.: ITA247920

Valid from: 2014-09-16
Valid until: 2019-09-15

Date, 2014-09-11

Hans-Heiner Junker

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

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