

EC-CERTIFICATE

Full Quality Assurance System
(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)
No. G1 09 09 70143 001

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.I.

Via L. da Vinci, 168, 20090 Trezzano sul Naviglio (MI), ITALY

Product Pressure regulators for medical gases.

Category(ies): Oxygen flowmeters

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 products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: ITA 193541

Valid until: 2014-09-15

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Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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