CERTIFICAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認証書 ◆ CERTIFICATE ◆ CERTIFIKAT

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 18 03 33230 025

Manufacturer:

Spencer Italia s.r.l.
Via Provinciale 12
43038 Sala Baganza (PR)
ITALY

Facility(ies):

Spencer Italia s.r.l.
Via Provinciale 12, 43038 Sala Baganza (PR), ITALY

Spencer Italia s.r.l.
Via Petitot 4, 43038 Sala Baganza (PR), ITALY

Spencer Italia srl
Via Lega dei Carrettieri 3, 43038 Sala Baganza (PR), ITALY

Spencer Italia s.r.l.
Via Provinciale 38, 43038 Sala Baganza (PR), ITALY

Product Category(ies):

Lung ventilators for emergency care, rescue masks, medical gases delivery systems for ambulance installation, infusion bag warming system

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.

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Stefan Preiß

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