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

Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 10 08 35193 011

Manufacturer:

REDAX s.r.l.
Via Volta 51
41037 Mirandola
ITALY

Facility(ies):

REDAX s.r.l.
Via Volta 51, 41037 Mirandola, ITALY

Redax S.r.l.
Zona Industriale A.S.I. Lotto 44, 91100 Trapani, ITALY

Product Category(ies):

Thoracic and post-operative drainage systems, blood recovery and auto-transfusion systems, portable vacuum units

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.

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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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