ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 079050 0011 Rev. 01

Holder of Certificate: **Redax S.p.A.**
Via Galileo Galilei 18
46025 Poggio Rusco (MN)
ITALY

Facility(ies): Redax S.p.A.
Via Galileo Galilei 18, 46025 Poggio Rusco (MN), ITALY

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of drainage systems, blood recovery and auto-transfusion systems, portable vacuum pumps and related accessories**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA1379473

Valid from: 2020-01-28
Valid until: 2023-01-27

Date, 2020-01-27

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Iarovoi Petru
Date: 2021.10.09 19:35:47 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 079050 0012 Rev. 00

Manufacturer: **Redax S.p.A.**
Via Galileo Galilei 18
46025 Poggio Rusco (MN)
ITALY

Facility(ies): Redax S.p.A.
Via Galileo Galilei 18, 46025 Poggio Rusco (MN), 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 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.: ITA1264102

Valid from: 2019-09-30
Valid until: 2024-05-26

Date, 2019-09-30

Stefan Preiß
Head of Certification/Notified Body

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

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