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 037570 0019 Rev. 00**

**Manufacturer:** **RanD S.p.A.**
Via Statale 12 n. 62
41036 Medolla (MO)
ITALY

**Facility(ies):** RanD S.p.A.
Via Statale 12 n. 62, 41036 Medolla (MO), ITALY

**Product Category(ies):** **Equipment for extracorporeal circulation and for perfusion of warmed fluids in intracorporeal cavities; disposable devices for extracorporeal circulation and cell separation; disposable devices for perfusion of fluids in intracorporeal cavities; infusion and drainage catheters for intracorporeal cavities.**

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.:** ITA1288738

**Valid from:** 2019-06-05
**Valid until:** 2024-05-26

**Date,** 2019-06-05

Stefan Preiß
Head of Certification/Notified Body


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

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