



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 13 07 83155 001

Manufacturer: **TECNOSERVICE GROUP S.r.l.**

Via G. Matteotti 19-21
80026 CASORIA (NA)
ITALY

Facility(ies): TECNOSERVICE GROUP S.r.l.
Via G. Matteotti 19-21, 80026 CASORIA (NA), ITALY

Product Category(ies): **Water purification systems,
reverse osmosis used in
haemodialysis**

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.: ITA 227962

Valid from: 2013-10-14

Valid until: 2018-10-13

Date, 2013-10-15

Hans-Heiner Junker



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

Page 1 of 1