



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 098154 0001 Rev. 01

Manufacturer:

Dr. J. Hänsler GmbH

Nordring 8
76473 Iffezheim
GERMANY

Facility(ies):

Dr. J. Hänsler GmbH
Nordring 8, 76473 Iffezheim, GERMANY

**Product Category(ies): Ozone generators, sterile vacuum bottles
and sterile transfer filter set for
Ozone-Oxygen-Therapy**

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.:

713156026

Valid from:

2019-04-14

Valid until:

2024-04-13

Date,

2019-04-09

Stefan Preiß