Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD
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

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

Digitally signed by Busuioc Anatol
Date: 2020.10.29 17:00:56 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT