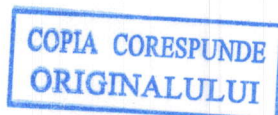




Handwritten signature



Product Service

Certificate

No. Q5 098154 0002 Rev. 01

Holder of Certificate: **Dr. J. Hänsler GmbH**
 Nordring 8
 76473 Iffezheim
 GERMANY

Facility(ies): Dr. J. Hänsler GmbH
 Nordring 8, 76473 Iffezheim, GERMANY

Certification Mark:



Scope of Certificate: **Design and Manufacture, Service and Distribution of Ozone Generators and Associated Disposables**

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.: 713145726

Valid from: 2019-04-09

Valid until: 2022-04-04

Date, 2019-04-09

S. Preis

Stefan Preis



Stefan Preis



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

COPIA CORESPUNDE
ORIGINALULUI

Innovative Geräte zur Ozontherapie

DR. HÄNSLER OZONOSAN
Made in Germany

Dr. J. Hänsler GmbH
OZONOSAN
Tel.: +49 7229 - 30 46 10
Fax: +49 7229 - 30 46 30
info@ozonosan.de

Declaration of Authorisation

Dr. J. Hänsler GmbH,

based in 76473 Iffezheim, Nordring 8, Germany

assign Romedcom SRL, based in Str_Sciusev, 16, of.6 Chisinau MD -2001, Republic of Moldova, as **authorized representative** in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to participate in public procurements with our medical equipment, to register, notify, renew or modify the registration of our medical devices on the territory of the Republic of Moldova.

Iffezheim Date: 23-10 2020

Signed: Dr. J. HÄNSLER GmbH
Elektrophysikalische Geräte
76473 Postfach 23 Nordring 8
76473 Iffezheim
Tel. +49 7229 30 46 0



Robert Viebahn, Managing Director

Dr. J. Hänsler GmbH Nordring 8 76473 Iffezheim Telefon +49 7229 30 46 10 Fax +49 7229 30 46 30 info@ozonosan.de www.ozonosan.de
Geschäftsführung: Robert Viebahn +49 7229 30 46 30 Geschäftsführer: Dr. J. Hänsler +49 7229 30 46 10
Bank für Geschäftskunden: BIC: BFSW33HAN Bank für Privatpersonen: BIC: BFSW33HAN
Bank für Geschäftskunden: BIC: BFSW33HAN Bank für Privatpersonen: BIC: BFSW33HAN

OZONOSAN-Prize 2008 Brigitte Fuchs Expanding cosmos Textile object

OZONOSAN
Prize for Art
2008

50 YEARS
OZONOSAN

Ozone-Oxygen Therapy

In Complementary Medicine

In the Following Diseases

- Arterial Circulatory disorders
Diabetic Foot, Infected Wounds
- Immunodeficiency and immunodysbalance
eg Infections, chronic forms of hepatitis
- supportive in rheumatoid arthritis
and inflammation of the joints
- Revitalization and prevention in
age related diseases

Mechanism of Action

- Ozone activates the metabolism
of the red blood cells
- Improves oxygen supply
- activates the cellular radical scavengers
- activates and modulates the immunesystem

Please contact your doctor.
Information for patients or scientific literature is provided by:
Medical Society for the Use of Ozone in Prevention and Therapy e.V.
Secretary's office: Nording 8, D-76473 Wehrheim
Fax: 0049-7229-30 46 30 www.ozone-association.com + www.ozonosan.de

