



Certificate

No. Q5 051287 0015 Rev. 00

Holder of Certificate: **Herrmann Apparatebau GmbH**



Im Höning 3
63820 Elsenfeld
GERMANY

Facility(ies):

Herrmann Apparatebau GmbH
Im Höning 3, 63820 Elsenfeld, GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Production, Installation and Servicing of Colon-Therapy Devices Including Speculum (single use), and Ozone Therapy Devices**

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.: 713128125

Valid from: 2018-09-03

Valid until: 2021-08-24

Date, 2018-09-03

Stefan Preiß



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 051287 0013 Rev. 01

Manufacturer:

Herrmann Apparatebau GmbH

Im Höning 3
63820 Elsenfeld
GERMANY

Facility(ies):

Herrmann Apparatebau GmbH
Im Höning 3, 63820 Elsenfeld, GERMANY

**Product Category(ies): Colon-Therapy Devices including
Disposables and Ozone-Therapy-Devices**

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.:

713139922

Valid from:

2018-10-18

Valid until:

2023-10-17

Date,

2018-10-11

Stefan Preiß