





Certificate No. Q5 051287 0015 Rev. 01

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Herrmann Apparatebau GmbH

Im Höning 3 63820 Elsenfeld GERMANY

Facility(ies):

Herrmann Apparatebau GmbH Im Höning 3, 63820 Elsenfeld, GERMANY

See Scope of Certificate

Certification Mark:



Design and Development, Production, Scope of Certificate: 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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?g=cert:Q5 051287 0015 Rev. 01

Report No.:	713207371
Valid from:	2021-08-26
Valid until:	2024-08-24

Date,

2021-08-26

Christoph Dicks Head of Certification/Notified Body

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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

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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: Valid until:

2018-10-18 2023-10-17

Date,

2018-10-11

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Stefan Preiß