



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

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Stefan Preiß



Page 1 of 1

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

TÜV®





Product Service

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

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Distribution Contract

1 Preamble

The below-mentioned contractual partners regulate in this Distribution Contract (subsequent "Contract") the distribution of the products listed under point 3 (Distribution relations). This Contract also regulates all questions concerning sales, instruction, maintenance, repairs and checks for operational safety of the products manufactured by Herrmann Apparatebau GmbH. Another part of this Contract will be the compliance with all requirements resulting from the EN ISO 13485 and the guidelines certificate 93/42/EWG.

In compliance with these requirements the contractual partners regulate the following:

2 Contractual partners

HERRMANN Apparatebau GmbH Im Höning 3 63820 Elsenfeld Germany

represented by the managing director Wolfgang Herrmann, business address like above (subsequent "supplier")

and

SOGNO S.R.L. 20 Academiei str. 2028 Kishinev Republic of Moldova

represented by the managing director Petru larovoi , business address like above (subsequent "distributor")

Customer identification number with H E R R M A N N Apparatebau GmbH: # 80179

(together subsequent "Parties")





regulation will be implemented which will best match the legal and economic purpose. The same will apply if a loophole becomes obvious which will require additional regulations.

- 15 Place of jurisdiction, applicable law
- 15.1 Place of jurisdiction for all conflicts between the Distributor and the Supplier will be the Obernburg courts (the business address of the Supplier is decisive). The Supplier can also claim on other courts having jurisdiction.
- 15.2 For this Contract as well as for single orders within the framework of this Contract exclusively German law to the exclusion of the United Nations Convention on Contracts for the International Sale of Goods (CISG) applies.

16 Utilisation of trademarks, know-how and other industrial property rights

The Distributor will be authorized to name itself as Distributor during the term of contract and to use according to contract the product descriptions, labels and other literary property of the Supplier if and to the extent that this is necessary for the distribution and the Contract Products. An assignment of authorization to third parties will be possible only by prior written consent.

17 Acceptance and handing-over of the Contract

Both Parties accept this Contract by signing it and confirm to have received a complete version of it together with the attachments.

Wolfgang Herrmann	Petru larovoi
Managing director	Managing director
HERRMANN Apparatebau GmbH	SOGNO S.R.L.
Elsenfeld, 01.07.2019	Kishinev. 02.08.2019
ERRMANN	Street St COME
pparatebau GmbH	A PASS
Im Höning 3 D=63820 Eksenfeld Fel. +49 (0) 8022/6581-3	Como
ax ±49 (0)/6022/6581-3	Ting.
Signature and stamp	Signature and stamp