ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 010918 0031 Rev. 01

Holder of Certificate: **Geister Medizintechnik GmbH**
Föhrenstr. 2
78532 Tuttlingen
GERMANY

Facility(ies):
Geister Medizintechnik GmbH
Föhrenstr. 2, 78532 Tuttlingen, GERMANY

Certification Mark:

tuv-sud.com/ps-cert

Digitally signed by Captari Alexandru
Date: 2022.10.18 15:48:02 EEST
Reason: MoldSign Signature
Location: Moldova

Scope of Certificate: **Design and development, production, distribution and repair of surgical instruments, surgical devices, sterile instruments and battery powered driver (drilling/sawing) and saw blades**

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?q=cert:Q5 010918 0031 Rev. 01

Report No.: 713189360

Valid from: 2020-11-01
Valid until: 2023-10-31

Date, 2020-10-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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 010918 0032 Rev. 00

Manufacturer:
Geister Medizintechnik GmbH
Föhrenstr. 2
78532 Tuttlingen
GERMANY

Facility(ies):
Geister Medizintechnik GmbH
Föhrenstr. 2, 78532 Tuttlingen, GERMANY

Product Category(ies):
Electro Surgical Units, HF-Electrodes, HF-Instruments, Sterile Instruments, Endoscopes, Suction and Irrigation Instruments, Retractors, Bulldog Clamps, Trocars and Battery-Powered Drivers (drilling/sawing) and Saw Blades

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.: 713155868

Valid from: 2019-09-23
Valid until: 2024-05-26

Date, 2019-09-23

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 010918 0033 Rev. 00

Manufacturer: **Geister Medizintechnik GmbH**
Föhrenstr. 2
78532 Tuttlingen
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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?q=cert:G11 010918 0033 Rev. 00

Report No.: 713180580

Valid from: 2020-10-19
Valid until: 2025-10-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-10-19

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Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 010918 0033 Rev. 00

Classification:	I
Device Group:	MDN 1208 - Non-active non-implantable instruments
Device Properties:	MDS 1006 - Reusable surgical instruments
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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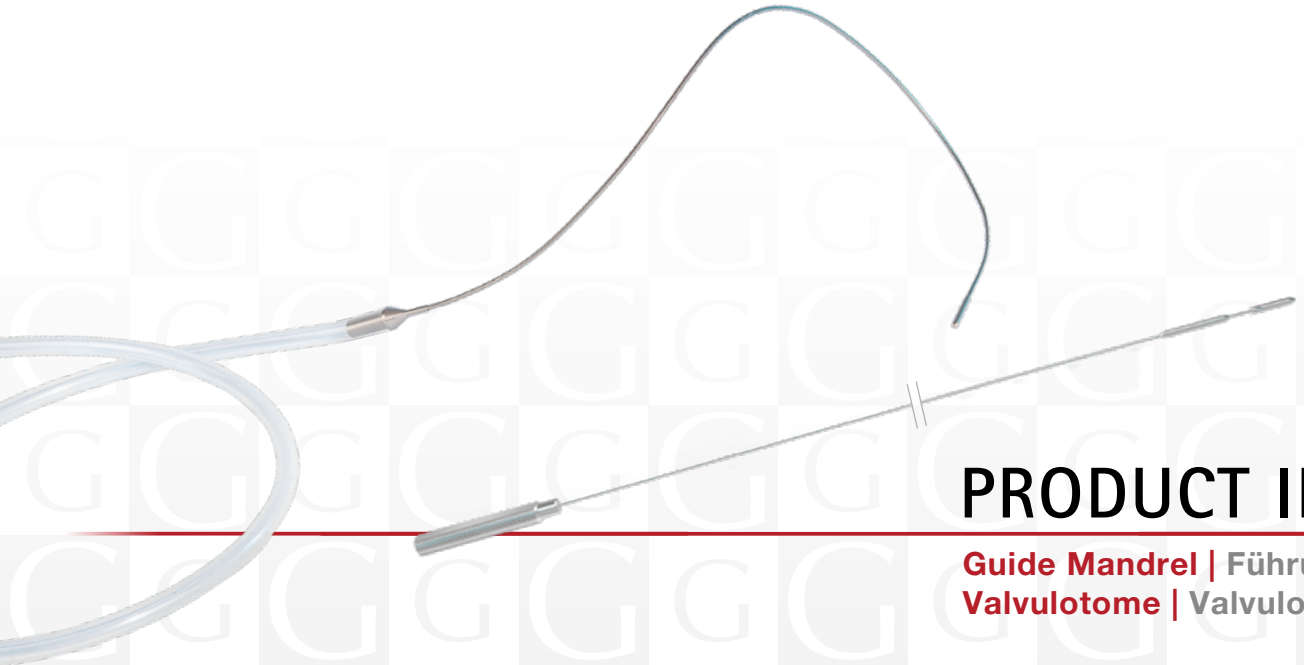
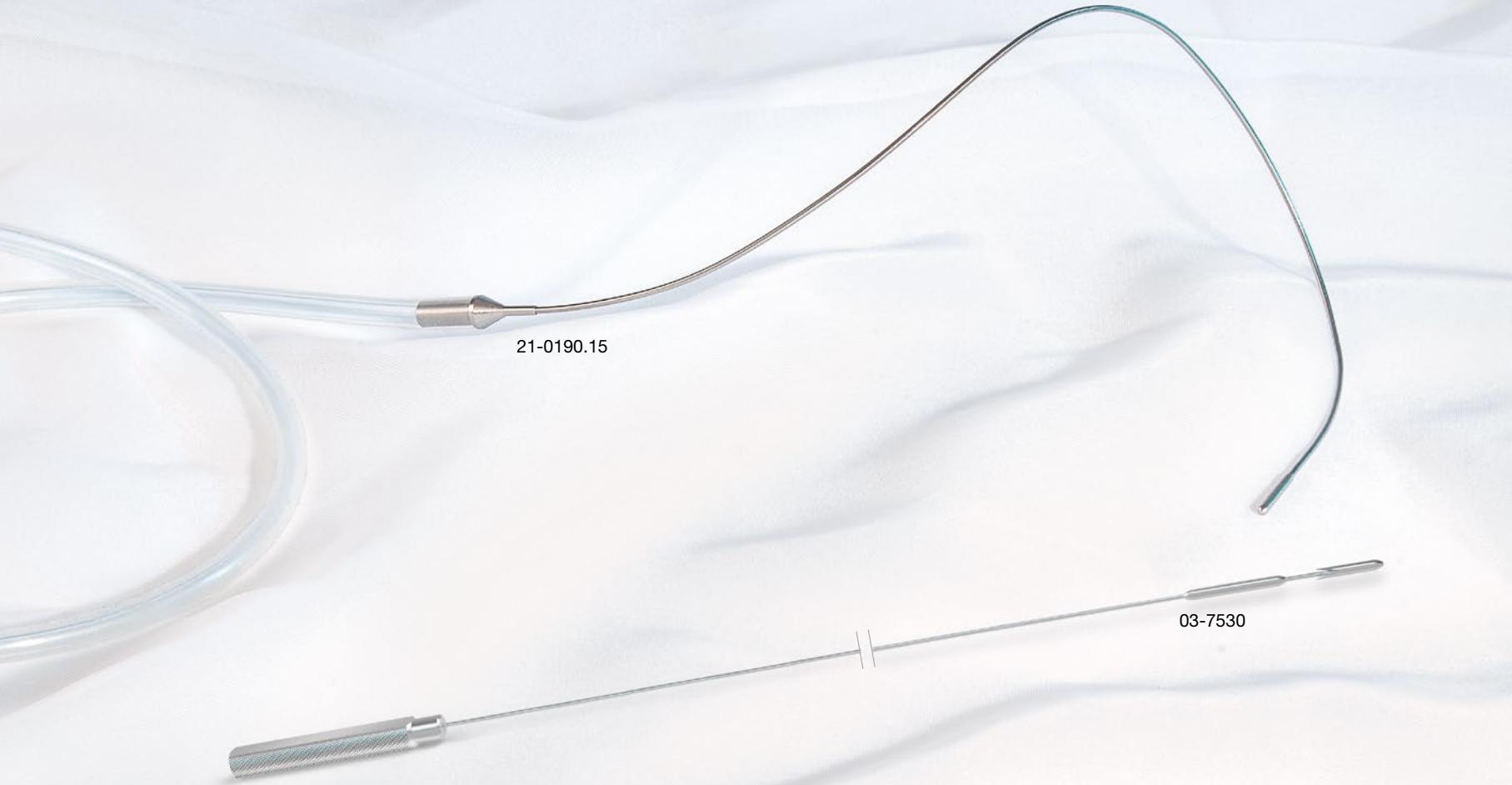
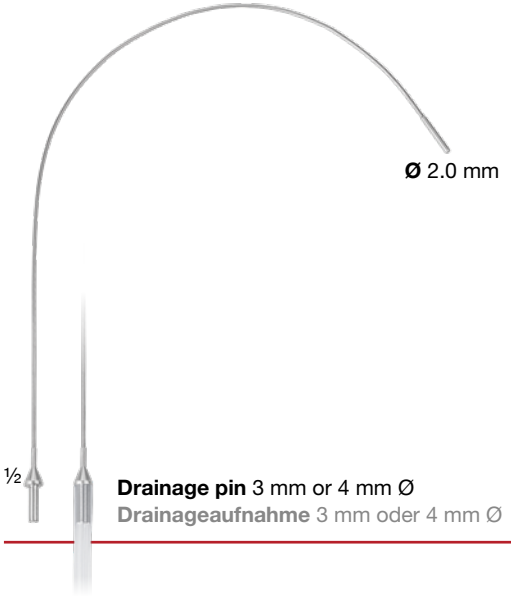


PRODUCT INFORMATION

Guide Mandrel | Führungsmandrin
Valvulotome | Valvulotom

Guide Mandrel, Valvulotome | Führungsmandrin, Valvulotom





Length 150 mm or 220 mm
Länge 150 mm oder 220 mm

Drainage pin 3 mm or 4 mm Ø
Drainageaufnahme 3 mm oder 4 mm Ø

Valulotome

Art.-No.	Length mm	Ø mm
03-7530	1000	2.0
03-7531	1000	2.5
03-7532	1000	3.0
03-7533	1000	3.5
03-7534	1000	4.0

Valvulotom

Art.-Num.	Länge mm	Ø mm
03-7530	1000	2.0
03-7531	1000	2.5
03-7532	1000	3.0
03-7533	1000	3.5
03-7534	1000	4.0

Guide Mandrel

for thin drainages
with 4 mm Ø drainage pin

Art.-No.	Length mm	Ø mm
21-0190.14	150	2.0
21-0190.15	220	2.0

with 3 mm Ø drainage pin

Art.-No.	Length mm	Ø mm
21-0191.14	150	2.0
21-0191.15	220	2.0

Führungsmandrin

Einführhilfe für dünne Drainagen
mit 4 mm Ø Drainageaufnahme

Art.-Num.	Länge mm	Ø mm
21-0190.14	150	2.0
21-0190.15	220	2.0

mit 3 mm Ø Drainageaufnahme

Art.-Num.	Länge mm	Ø mm
21-0191.14	150	2.0
21-0191.15	220	2.0

Clamp

for fixation, storage and processing

Art.-No.	Description
77-9990	tension area 0-10 mm

Klemme

zur Fixierung, Lagerung und Aufbereitung

Art.-Num.	Description
77-9990	tension area 0-10 mm

* **bold** = shown

Tunneler Set complete
Tunnelierer Set komplett

Art.-No.	Ø mm
03-5354	8 / 10
03-5355	10 / 12
03-5356	12 / 14

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