

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

Baholzer Endoskopie-Systeme GmbH & Co. KG
Neckartal 100
78628 Rottweil
Germany

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-05-07

Expiry date: 2023-10-07

Report No.: 7307PS05F
Process No.: QS - 7307
Certificate No.: 7307GB410200507

Hamburg, 2020-05-07

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 7307
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Topie Systeme
GmbH
100
Germany
1285699
96083

List of products / product categories included in the scope of certificate**Instruments and devices in the field of endoscopy**

- HF-Instruments
- HF-Electrodes
- Rigid endoscopes
- Semiflexible endoscopes
- Suction- and irrigation pumps
- Tubing sets for suction and irrigation pumps
- Spikes for suction and irrigation pumps
- Insufflators
- Tube sets for insufflators
- CO₂ containers for insufflators
- Cannulas for suction, irrigation and insufflation
- Trocar systems
- Endoscopic shafts
- Endoscopic obturators
- Guiding tubes
- Bridges
- Endoscopic tubes
- Irrigation taps
- Needles
- Shaver blades
- Bladder syringes
- Flexible endoscopes

– End of list –

This appendix is integral part of the above-referenced certificate.
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TỔNG LÃNH SỰ QUÁN NƯỚC CHXHCN VIỆT NAM
tại Frankfurt am Main, CHLB Đức

1. Quốc gia: **Việt Nam**
Country:
- Giấy tờ, tài liệu này**
This public document
2. do Ông (Bà): **Ingrid Schatter** ký
has been signed by:
3. với chức danh: **Cán bộ phụ trách**
acting in the capacity of:
4. và con dấu của: **Phòng Công nghiệp và Thương mại**
bears the seal/stamp of: KV Schwarzwald-Baar-Heuberg
được chứng nhận / hợp pháp hóa lãnh sự
Certified
5. tại: **Frankfurt** 6. ngày: **09/07/2020**
at: the:
7. Cơ quan cấp: **Tổng lãnh sự quán Việt Nam tại Frankfurt/Main**
by:
8. Số: **914/2020/CN-HPHLS**
No:

Lãnh sự/ Consul



Nguyễn Nam Hải