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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 106138 0002 Rev. 00**

**Manufacturer:** **Marflow AG**  
 Soodstrasse 57  
 8134 Adliswil, Zurich  
 SWITZERLAND

**Product Category(ies):** Class IIb  
 Double J stent & set  
 Class IIa  
 PCN catheter & set  
 Ureteral catheter  
 Malecot catheter  
 Re-entry malecot catheter  
 Suprapubic catheter  
 Braided shaft catheter  
 Dual lumen catheter  
 Facial dilator  
 Amplatz dilator & set  
 Ureteral dilator & set  
 Ureteral balloon dilator  
 Double J stent & set  
 Mono J stent  
 Endopyelotomy stent  
 Guidewire  
 IP Needle  
 Chiba needle  
 Stone basket  
 Perk basket

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.:** IND20190101

**Valid from:** 2020-04-03  
**Valid until:** 2024-05-26

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

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



Legalization see reverse side

**Official Certification**

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich, identified by identity card.

Zürich, 8th April 2020  
BK no. 1027ff  
Fee CHF 20.00



**NOTARIAT ENGE-ZÜRICH**

Andreas Bachmann, Notary Public

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Notariat Enge – Zürich Kanton Zürich
5. In / at 8090 Zürich / Zurich
6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich  
by the Chancellery of State of the Canton of Zurich
8. unter Nr. / under N° 1179274/2020
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S. Overkott





Product Service

**Certificate**  
 No. Q5 106138 0001 Rev. 00

**Holder of Certificate:** **Marflow AG**  
 Soodstrasse 57  
 8134 Adliswil, Zurich  
 SWITZERLAND

**Facility(ies):** Marflow AG  
 Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND



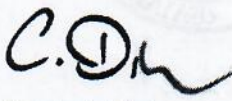
**Scope of Certificate:** Design and Development, Manufacture and Supply of Medical Disposables, Surgical Tools, Equipment & Accessories in the Field of Urology, Gastroenterology, Radiology, Gynaecology & Cardiology.

**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.:** IND20190101

**Valid from:** 2020-04-03  
**Valid until:** 2023-04-02

**Date,** 2020-04-03   
 Christoph Dicks  
 Head of Certification/Notified Body





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Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in class I in sterile conditions, sterilized systems or procedure packs)

**No. G1S 106138 0003 Rev. 00**

**Manufacturer:**

**Marflow AG**

Soodstrasse 57  
8134 Adliswil, Zurich  
SWITZERLAND

**Product**

**Category(ies):**

**Class Is**

Urine bag connector

Penile clamp

Evacuator

IUI catheter without syringe

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:**

IND20190101

**Valid from:**

2020-04-03

**Valid until:**

2024-05-26

**Date,**

2020-04-03

Christoph Dicks  
Head of Certification/Notified Body

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Bestätigt / Certified

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S. Overkott