



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**

**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:**

2019-10-22

**Valid until:**

2024-10-21

**Date,**

[#ISU\_DT#]

Stefan Preiß

Head of Certification/Notified Body

Draft From CBW 2.0 - Production System (Build - 20190829.1)



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**No. G1 106138**

**Facility(ies):**

Marflow AG

Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

-/-

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# Certificate

No. Q5 106138

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

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

**Certification Mark:**



**Scope of Certificate:** **The Design, 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:** 2019-10-22  
**Valid until:** 2022-10-21

**Date,** [#ISU\_DT#]

Stefan Preiß  
Head of Certification/Notified Body

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