



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

*T. Wacker*

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

**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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(Convention de la Haye du 5 octobre 1961)

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Country: Swiss Confederation, Canton of Zürich  
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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





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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

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2020-04-03

**Valid until:**

2024-05-26

**Date,**

2020-04-03

Christoph Dicks  
Head of Certification/Notified Body

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