



**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

**APOSTILLE**

(Convention de la Haye du 5 octobre 1961)

1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich  
Country: Swiss Confederation, Canton of Zürich  
Diese öffentliche Urkunde / This public document

2. ist unterschrieben von  
has been signed by Andreas Bachmann

3. in seiner Eigenschaft als  
acting in the capacity of Notary Public

4. sie ist versehen mit dem Stempel/Siegel des (der) – bears the stamp/seal of  
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

9. Stempel/Siegel, Stamp/seal

10. Unterschrift / Signature [Signature]



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

**Certification Mark:**



**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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*[Handwritten signature]*

S. Overkott



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

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

TUV®

Legalization see reverse side

TÜV SÜD  
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認 證 證 書 ♦ CERTIFICADO ♦ CERTIFICAT

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S. Overkott