



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. Waackner

Page 1 of 3

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

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

TÜV®

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 Brunastrasse 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	
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5. In / at 8090 Zürich / Zurich	Bestätigt / Certified 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



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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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.

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2020-04-03

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2024-05-26

Date,

2020-04-03

Christoph Dicks
Head of Certification/Notified Body

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