



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

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

TÜV SÜD
 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

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

S. Overkott



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
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° 1179275/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

Bestätigt / Certified

6. am / the 08.04.2020



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

Page 1 of 2

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 ♦ CERTIFIKAT ♦ CERTIFICADO ♦ CERTIFICAT

A4 / 07.17

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

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

Bestätigt / Certified

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° 1179273/2020

9. Stempel/Siegel, Stamp/seal 10. Unterschrift / Signature



S. Overkott