Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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

Digitally signed by Bunic Gheorghe
Date: 2023.11.20 13:05:23 EET
Reason: MoldSign Signature
Location: Moldova

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

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 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

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° 1179274/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

S. Overkott

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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:

tuv-sud.com/ps-cert

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

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

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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

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

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

Legalization see reverse side

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ 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 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)

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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

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Ackermann Instrumente GmbH
Eisenbahnstraße 65 - 67
78604 Rietheim-Weilheim
Germany

for the scope

Devices for Endoscopy, Scopes, Cannulas,
Suction and Irrigation Systems, Shaver- Systems
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-07-10
Valid until	2024-05-26
Registration no.	D1458100002
Report no.	P20-00999-178914
Stuttgart	2020-07-10

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1458100002 Date 2020-07-10 Page 1 of 1

Product category	Product	Class
Devices for Endoscopy	Sheath Systems and Accessories	IIa
	Forceps	IIa
	Stone Baskets	IIa
	Electrosurgical Instruments	IIb
Endoscopes	Rigid Endoscopes and Accessories	IIa
Cannulas	Trocars and Accessories	IIa
	Insufflation Cannulas	IIa
Suction and Irrigation Systems	Suction and Irrigation Instruments and Accessories	IIa
	Suction and Irrigation Cannulas	IIa
	Suction and Irrigation Units and Accessories	IIa
Shaver- Systems	Shaver Blades	IIa
	Shaver- Units and Accessories	IIa

Head of Certification Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

KAF GRUP SAĞLIK HİZMETLERİ	EC DECLARATION			
	Document No	**Issue Date**	**Revision No**	**Revision Date**
	TD. 03.51	10.06.2019	03	26.05.2021

CE

EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/EEC

Company Name	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ
Authorized Person / Title	:	Gökmen Aytin / General Manager
Head Office Address	:	Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat 14 D:83 Küçükçekmece/İstanbul/TURKEY
Phone Number	:	Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN
Web	:	+90 212 471 42 00
Mail	:	www.kafgrup.com
Production Address	:	info@kafgrup.com
Brand Information	:	ONEGEL

as, the models and GMDN Codes of our **Onegel Lubricat Gel With Lidocaine (Sterile)** products specified in the **TD.03.22 Product Model and GMDN Code Table**;

Product List

Reference Code	Product Name	Substance	Volume	GMDN CODE	Class
KAF G27-6	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	6 ml	37717	III

KAF GRUP
SAĞLIK HİZMETLERİ

EC DECLARATION

Document No	Issue Date	Revision No	Revision Date
TD. 03.51	10.06.2019	03	26.05.2021

KAF G27-11	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	11 ml	37717	III
KAF G27-12,5	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	12,5 g	37717	III

EN ISO 13485:2016
EN 1041:2008+A1:2013
EN ISO 10993-6:2016
EN ISO 10993-12:2012
EN ISO 14644-3:2019
EN ISO 11607-2:2018
EN ISO 11137-1:2015
EN 868-5:2017
ASTM F 1929-15
EN 14698-2:2003
European Pharmacopoeia (Ph. Eur.) 10th Edition
Meddev 2.7.1 rev 4

EN ISO 15223-1:2016
EN ISO 62366-1:2015
EN ISO 10993-10:2013
EN ISO 14644-1:2015
EN ISO 14644-4:2001
EN ISO 11737-1:2018
EN ISO 11137-2:2015
EN ISO 10993-5:2009
ASTM F 88/F88 M
EN ISO 7886-1:2018
Meddev 2.12-1 rev.8

EN ISO 14971:2019
EN ISO 10993-1: 2018
EN ISO 10993-3:2014
EN ISO 14644-2:2015
EN ISO 11607-1:2018
EN ISO 11737-2:2009
EN 556-1:2001/AC:2006
ASTM F 1980-16
EN ISO 14698-1:2003
USP 43-NF 38
Meddev 2.12-2 rev 2

Manufactured to harmonized standards, and we declare that it complies with the provisions of the

KAF GRUP SAĞLIK HİZMETLERİ	EC DECLARATION			
	Document No	**Issue Date**	**Revision No**	**Revision Date**
	TD. 03.51	10.06.2019	03	26.05.2021

Medical Device Directive 93/42/EEC Annex II (4)
Full Quality Assurance Certificate
Class III
(93/42/AT Annex IX, Rule 13 ve Rule 5)

Authorized European Representative: Anxietas Ug,
Industriestrasse 43,
50389 Berzdorf
Köln/GERMANY
Köln HRB: 106071
info@anxietas.de

GMND Code	37717- Transurethral instrument lubricant
GMDN Description	A lubricant designed to facilitate the manipulation of a surgical instrument within the body during endoscopic processes of the urinary canal. This device cannot be reutilized after application.

Notified Body	:	TÜRK STANDARTLARI ENSTİTÜSÜ
Notified Body Address	:	Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA
Notified Body Identity No	:	1783
Design Certificate No	:	1783-MDD-239
Issue Date of Design Certificate	:	24.05.2021
Validity Date of Design Certificate	:	26.05.2024
Design Inspection Report Number	:	2203-MDD-173/2020-02
Quality Certificate No	:	1783-MDD-238
Issue Date of Quality Certificate	:	24.05.2021
Validity Date of Quality Certificate	:	26.05.2024
Quality Inspection Report Number	:	2203-MDD-173/2020-02
Company Declaration Date	:	26.05.2021
Place of Declaration	:	İSTANBUL-TURKEY
Declarant	:	Gökmen Aytin / GENERAL MANAGER
Approval	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC. LTD. ŞTİ. Atakent Mh. 221. Sk. No:3A Rota Ofis A Blok D.83 Küçükçekmece/İSTANBUL Tel: 0212 471 42 00 Fax: 0212 471 42 01 Halkalı V.D.: 486 053 3864