3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2013-MDD/QS-032

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. certifies that the medical device of Class IIa & IIb,

Medical Devices for Gastroenterology
(for detailed list refer to Annex, pages 1 to 3)

manufactured by company

Marflow AG
Soodstrasse 57, CH-8134 Adliswil, Zürich, Switzerland

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Reports No. 310121A and 310121B, and the Final protocol No. 310121b/2013 that is enclosed to this certificate.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until August 26th, 2019 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

In Bratislava, on August 27th, 2013

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarína Srdošová
Responsible to act on behalf of NB 2265

Digitally signed by Bunic Gheorghe
Date: 2019.04.16 15:57:27 EEST
Reason: MoldSign Signature
Location: Moldova

TRANSGLOBAL QUALITY ASSESSORS LLP

Management System Certificate

Certificate No. MD.QMS.91.006.06.16

This is certify that

Marflow AG

at

Soodstrasse 57, CH-8134 Adliswil, Zürich, Switzerland.

has been found to conform to Management System Standard

ISO 13485: 2003

This certificate valid for the following product / service ranges:

DESIGN AND MANUFACTURE OF NON-ACTIVE AND ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES FOR UROLOGY AND GASTROENTEROLOGY

Internal Certification : 23.06.2016
Valid until : 22.06.2019

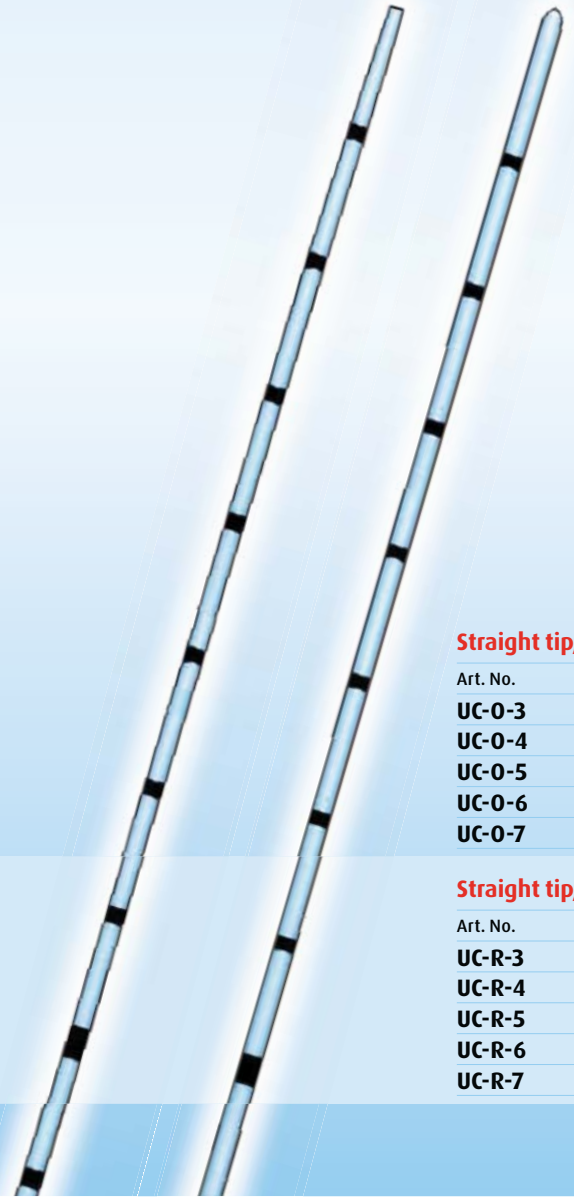
(Authorized Signatory)
Transglobal Quality Assessors LLP

This is an accredited certificate authorised for issue by Accreditation Services for certifying bodies (Europe) Limited, who have assessed Transglobal Quality Assessors LLP Located at PUNE, INDIA, against defined criteria and in cognisance of ISO 17021, "Conformity Assessment Requirements for bodies providing audit and certification of management systems". This certificate is only valid when confirmed by register listed in the International register of Quality Assessed Organisation : www.irqao.com

Ureteral Catheters

To inject contrast liquid

With stylet



Made of PEBAX
Class IIa device
For single use only

Straight tip, open

Art. No.	Size (Fr/CH)	Length (cm)
UC-O-3	3	70
UC-O-4	4	70
UC-O-5	5	70
UC-O-6	6	70
UC-O-7	7	70

Straight tip, closed

Art. No.	Size (Fr/CH)	Length (cm)
UC-R-3	3	70
UC-R-4	4	70
UC-R-5	5	70
UC-R-6	6	70
UC-R-7	7	70

MarFlow®

Ureteral Catheters

To inject contrast liquid

With stylet

Made of PEBAX
Class IIa device
For single use only

Angled tip open (Tiemann)

Art. No.	Size (Fr/CH)	Length (cm)
UC-AO-3	3	70
UC-AO-4	4	70
UC-AO-5	5	70
UC-AO-6	6	70
UC-AO-7	7	70

Angled tip closed (Tiemann)

Art. No.	Size (Fr/CH)	Length (cm)
UC-AR-3	3	70
UC-AR-4	4	70
UC-AR-5	5	70
UC-AR-6	6	70
UC-AR-7	7	70

Cone tip open

Art. No.	Shaft (Fr/CH)	Cone (Fr/CH)	Length (cm)
UCC-5/8	5	8	70
UCC-6/10	6	10	70
UCC-7/12	7	12	70