MED CERT®

Professional. Flexible. Medical Only.

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

MTW - Endoskopie W. Haag KG
Goldsbergstr. 18
46487 Wesel
Germany

Digitally signed by Bunic Gheorghe
Date: 2019.12.20 13:42:22 EET
Reason: MoldSign Signature
Location: Moldova

has introduced, applies and maintains a Quality Assurance System for the aspects of manufacture **concerned with securing and maintaining sterile conditions**
for the products / product categories:

Medical devices as per attachment

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certificate is valid until: 01 July 2020

Report No.: 1484FS18F
Process No.: QS – 1484
Certificate No.: 1484GB415150901

Hamburg, 01 September 2015

MEDCERT Certification Body
(Dr. Andreas Schich)

MEDCERT Identification No.: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

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Attachment
EC-Certificate of Conformity
QS – 1484

This attachment is valid only in connection with certificate No: 1484GB415150901

- **Antifoaming Needles**
- **Aspiration Needles**
- **Balloons for Echo Endoscopy**
- **Biopsy Cannulas**
- **Biopsy Forceps**
- **Biopsy Valves**
- **Cytology Brushes**
- **ERCP-Catheters**
- **Foreign Body Protector Hoods**
- **Foreign Body Removing Forceps, Polypotomes**
- **Lithotriptors**
- **Spray Catheters**
- **Wash-Out Probes**

Hamburg, 01 September 2015

MEDCERT Certification Body
(Dr. Andreas Schich)

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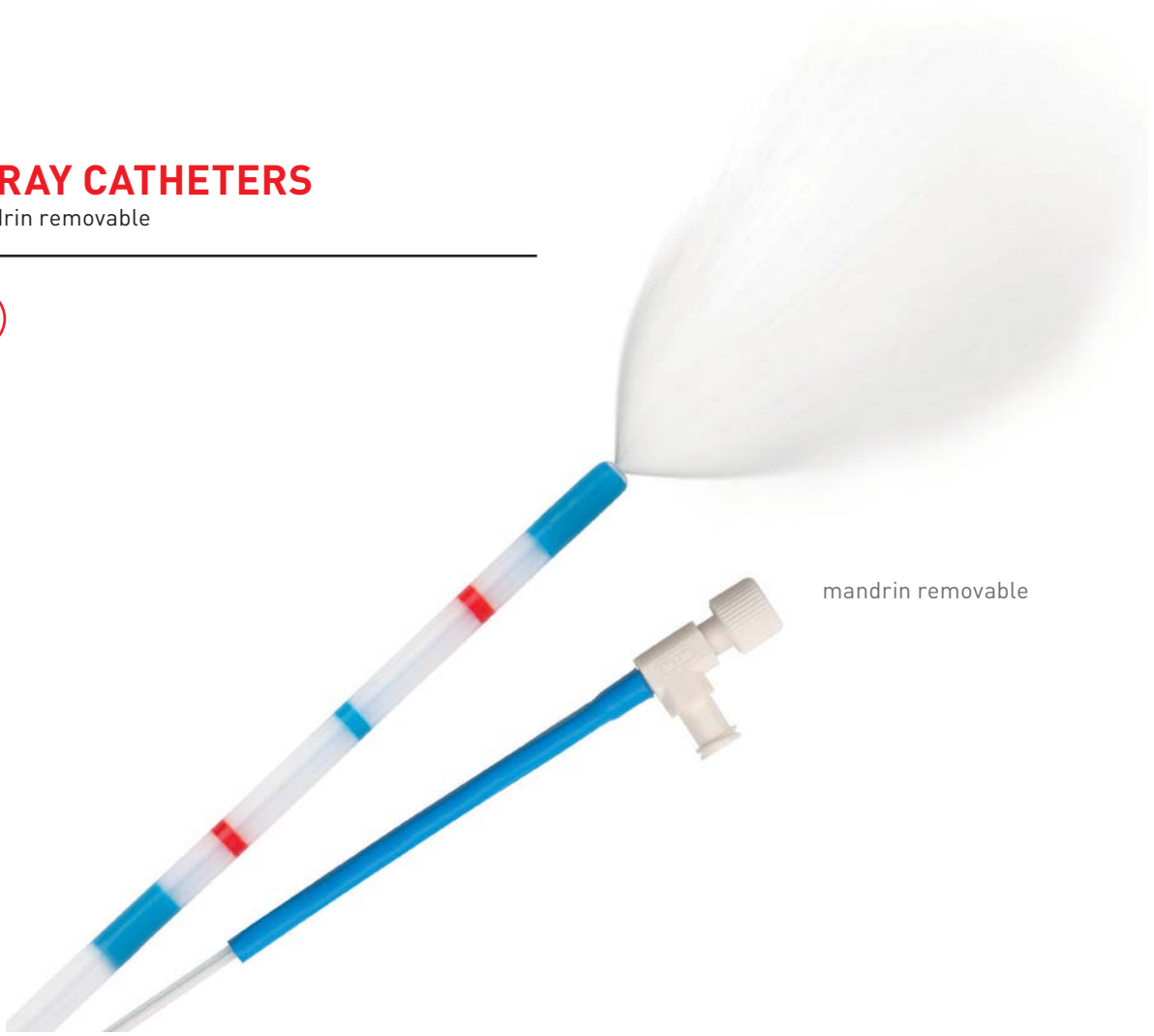
ZLG-BS-237.10.15

SPRAY CATHETERS

mandrin removable



mandrin removable

Article no.	Diameter mm	Length cm	
99 11 01 01 21 0	1,8	120	
99 13 01 01 21 0	1,8	250	
99 01 01 31 0	2,3	215	
99 13 01 01 31 0	2,3	250	

Figure shows article REF 99 01 01 31 0

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

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: 2019-10-22
Valid until: 2024-10-21

Date, [#ISU_DT#]

Stefan Preiß
Head of Certification/Notified Body

Draft From CBW 2.0 - Production System (Build - 20190829.1)

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

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

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

Facility(ies):

Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

-/-

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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

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: 2019-10-22
Valid until: 2024-10-21

Date, [#ISU_DT#]

Stefan Preiß
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

Facility(ies):

Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

-/-

Draft From CBW 2.0 - Production System (Build - 20190829.1)

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

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

Product Service

Certificate

No. Q5 106138

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: **The Design, 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: 2019-10-22
Valid until: 2022-10-21

Date, [#ISU_DT#]

Stefan Preiß
Head of Certification/Notified Body

Draft From CBW 2.0 - Production System (Build - 20190829.1)

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

Multiband Ligator

Barrel with 6 bands

Used for endoscopic ligation of Esophageal varices at or above gastroesophageal junction

Fits on wide range of endoscopes
Second last Band light colour

Standard Band Ligator
requires 9.5 to 11.2 mm endoscope diameter

Paediatric Band Ligator
requires 8.0 to 9.5 mm endoscope diameter

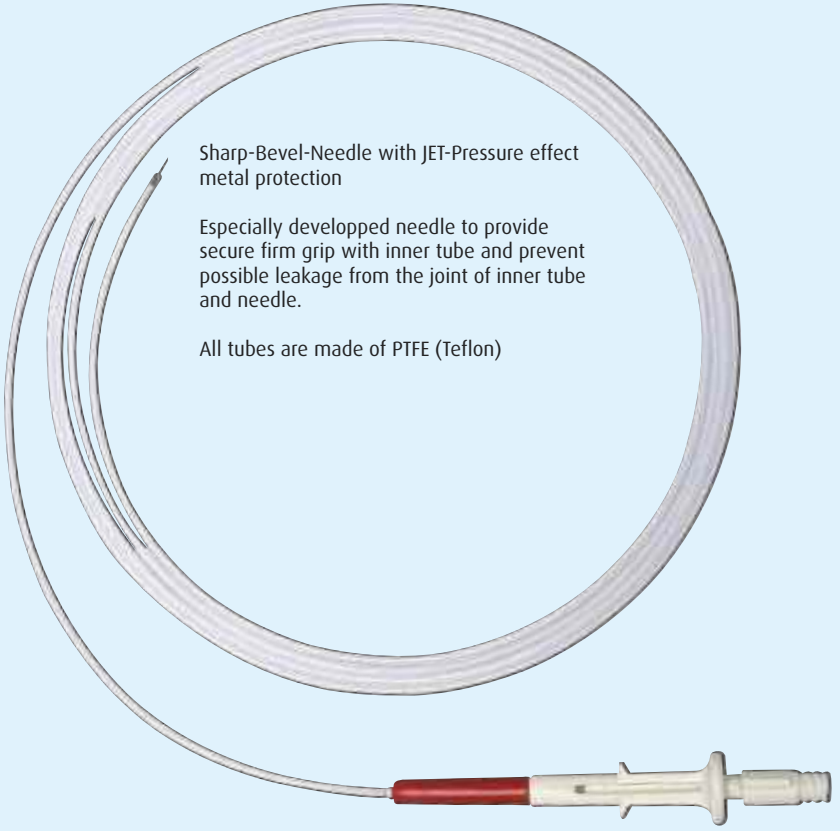
	Art. No.	Product name
Standard	SGK-6	Set incl. Applicator barrel, thread puller and flushing needle
	SGB-6	Barrel and thread puller only
Paediatric	SGK-6-S	Set incl. Applicator barrel, thread puller and flushing needle
	SGB-6-S	Barrel and thread puller only

Class IIa – Unsterile – for single use only

MarFlow® MEDICAL EQUIPMENT

Sclerotherapy Injection Needles

Used for endoscopic injection into esophageal varices above esophageal junction



Sharp-Bevel-Needle with JET-Pressure effect metal protection

Especially developped needle to provide secure firm grip with inner tube and prevent possible leakage from the joint of inner tube and needle.

All tubes are made of PTFE (Teflon)

Art. No.	Product name	Needle gauge	Needle length	Working length	Working Channel Ø
SGN-2321	Sclerotherapy Needle	21G	7 mm	170 cm	2.8 mm
SGN-2321-C	Sclerotherapy Needle	21G	7 mm	230 cm	2.8 mm
SGN-2323	Sclerotherapy Needle	23G	7 mm	170 cm	2.8 mm
SGN-2323-C	Sclerotherapy Needle	23G	7 mm	230 cm	2.8 mm
SGN-2324	Sclerotherapy Needle	24G	4 mm	170 cm	2.8 mm
SGN-2324-C	Sclerotherapy Needle	24G	4 mm	230 cm	2.8 mm

C = Colono

Class IIa – Unsterile – for single use only

BIOHIT *Helicobacter pylori* UFT300 quick test

Ultra-fast H. pylori detection from a biopsy
The Biohit *H. pylori* UFT300 is a true quick test for the detection of *H. pylori* from a biopsy specimen. The biopsy taken during gastroscopy can be tested immediately to diagnose *H. pylori* infection or to determine the success of eradication therapy. The test results are ready in only 5 minutes enabling diagnosis and reporting at the same time. This saves the patient from an unnecessary visit to the doctor for hearing the test results. The Biohit *H. pylori* UFT300 quick test has excellent sensitivity and specificity which makes it a highly reliable and accurate tool for diagnostics.

One-step test procedure
The Biohit *H. pylori* UFT300 quick test is easy and effortless to use. The biopsy specimen is placed into the test tube and mixed with the test reagent. Clear colour change indicates the presence of in the specimen within 5 minutes. The closed test system of the UFT300 quick test makes the test procedure safe and hygienic for the user, and the interpretation of the results doesn't require specialist training.

***Helicobacter pylori* UFT300 quick test**
- Ready-to-use test kit
- Results ready in 5 min (both positive and negative)
- Storage in room temperature
- Sensitivity 94,5%, Specificity 100%
- Testing and reporting during one appointment

Helicobacter pylori Quick test		
Cat. No.	**Product**	**Qty**
602019	UFT300 quick test kit	50 tests
602021	UFT300 quick test kit	100 tests
602017	Positive control	1

In the United States and Japan for research use only.

BIOHIT HealthCare

Innovating for Health

CE

EC Declaration of Conformity

I, the undersigned, hereby declare that the Product(s)

Helicobacter pylori IgG Elisa, Cat. No. 601 040.02
Gastrin-17 Elisa, Cat. No. 601 035
Pepsinogen I Elisa, Cat. No. 601 010.01
Pepsinogen II Elisa, Cat. No. 601 020.02
Lactose Intolerance, quick test, Cat. No.s 602 010 (25 tests) and 602 012 (10 tests)
Lactase CONTROL+, Cat. No. 602 018
***Helicobacter pylori*, quick test, Cat. No. 602 015**
BIOHIT *Helicobacter pylori* UFT300, quick test
Cat. No.s 602 005, 602 005PLA (5 tests), 602 019, 602 019PLA (50 tests)
and 602 021 (100 tests)
***Helicobacter pylori* CONTROL+, Cat. No. 602 017**
BIOHIT Celiac quick test, Cat. No. 602 070
BIOHIT ColonView, Cat. No. 602 250.02
BIOHIT Calprotectin ELISA, Cat. No. 602 260
BIOHIT Extraction Tubes, Cat. No. 602 270
BIOHIT Active B12 (Holotranscobalamin), Cat. No. 602 290
Gastrin-17 Stabilizer, Cat. No.s 601 050 (1 x 5,5 ml) and 601 051 (5 x 5,5 ml)
GastroPanel: Pepsinogen I, Pepsinogen II, *H. pylori*, Gastrin-17 Elisa, Cat No. 601 300

Conform to the applicable provisions of EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices. Category: Other/General devices.

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (excluding point 6) of the Directive.

Standards applied:

ISO 9001:2008, ISO 13485:2003

Certificate No. 111839-2012-AQ-FIN-FINAS issued by DNV on 09 February 2015

ISO 14001 Certificate No. 111840-2012-AE-FIN-FINAS issued by DNV on 09 February 2015

ISO 13485:2003 Certificate No. CERT-0075001 issued by QMI SAI Global on 08 March 2015

Signed: _____ Date: 24th June, 2015

Name: **Semi Korpela**

Title: **President & CEO**

Company: **Biohit Oyj, Laippatie 1, 00880 Helsinki, Finland**

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
256415-2018-AQ-FIN-FINAS

Initial certification date:
05 June 1997

Valid:
29 August 2018 - 28 February 2021

This is to certify that the management system of

Biohit Oyj

Laippatie 1, FI-00880 Helsinki, Finland

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:
Design/development, manufacture, marketing, and sales/distribution of acetaldehyde binding medical devices and in vitro diagnostic medical devices used in the diagnosis of risk of gastric cancer, immune status, disease/health status, autoimmune status, gastric disorders, including near patient in vitro diagnostic devices.

Place and date:
Espoo, 29 August 2018

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

For the issuing office:
DNV GL Business Assurance Finland Oy Ab

Kimmo Haarala
Management Representative