

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

has introduced, applies and maintains a Quality Assurance System
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 II excluding section 4

This certificate is valid until: 01 July 2020

Report No.: 1484FS18F
Process No.: QS – 1484
Certificate No.: 1484GB410150901

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

Attachment
EC-Certificate of Conformity
QS – 1484

This attachment is valid only in connection with certificate No: 1484GB410150901

- **Aspiration Needles**
- **Balloon Catheters**
- **Baskets for foreign bodies**
- **Biopsy Cannulas**
- **Biopsy Forceps**
- **Check Valves**
- **Coagulation Probes**
- **Cyst Drainage Enlarger Sets (Stents, Cyst; Guiding Catheters, Pushers)**
- **Cyst Drainage Sets (Stents, Cyst; Cystostomes; Pushers)**
- **Cystostomes**
- **Dilatation Catheters**
- **ESD-Knives**
- **Guide Wires**
- **HF-Knives, HF-Needles**
- **High Frequency Clamps**
- **Hot Biopsy Forceps**
- **Injection Needles**
- **Lithotomy Baskets**
- **Lithotripters**
- **Nasobiliary Drainage Catheters**
- **Papillotomes**
- **Polypectomy Snares**
- **Positioning Aids (Introducer Systems, Guiding Catheters, Pushers, Extraction Catheters, Extraction Snares)**
- **Ring Knife Sets (Stents, Cyst; Ring Knives; Pushers)**
- **Ring Knives**
- **Rinsing Apparatuses**
- **Stents, Bile**
- **Stents, Cyst**
- **Stents, Pancreas**
- **Stent-Sets, Bile (Stents, Bile; Guiding Catheters; Pushers)**
- **Stent-Sets, Pancreas (Stents, Pancreas; Guiding Catheters; Pushers)**

Hamburg, 01 September 2015


MEDCERT Certification Body
(Dr. Andreas Schich)



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Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

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

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

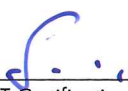
The compliance of the Quality Assurance System with the below mentioned requirements of the
Council Directive 93/42/EEC was verified by an audit:

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



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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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Certificate

The Certification 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

With its facilities as per attachment 1

has introduced, applies and maintains a Quality Management System in the area of:

**Design, manufacture, final inspection, distribution and repair of
instruments for endoscopic use and related accessories**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

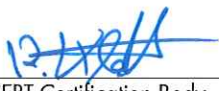
EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 01 July 2021

Report No.: 1484FS22F
Process No.: QS – 1484
Certificate No.: 1484GB445181029

Hamburg, 29 October 2018


MEDCERT Certification Body
(Rainer Klatt)

 **DAkkS**
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

Attachment 1
Certificate
QS – 1484

This attachment is valid only in connection with certificate No.: 1484GB445181029

Facilities

MTW – Endoskopie W. Haag KG
Sebastianusstr. 33
46487 Wesel
Germany

MTW – Endoskopie W. Haag KG
Sebastianusstr. 35
46487 Wesel
Germany

MTW – Endoskopie W. Haag KG
Sebastianusstr. 52
46487 Wesel
Germany

Hamburg, 29 October 2018



MEDCERT Certification Body
(Rainer Klatt)