

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


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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 aspects of manufacture
concerned with securing and maintaining sterile conditions
for the products / product categories:

Medical devices as per attachment

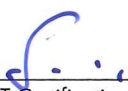
The compliance of the Quality Assurance System with the below mentioned requirements of the
Council Directive 93/42/EEC was verified by an audit:

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
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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



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SERTİFİKA

TÜRCERT Sertifikasyon Merkezi
iş bu belge ile/TÜRCERT Certification Body
with this document.

TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TİC. A.Ş.

YAKUPLU MAH. BİRLİK CAD. NO:32/1 BEYLİKDÜZÜ İSTANBUL TÜRKİYE

şirketinin;/ of the company

RÖNTGEN SOLÜSYONLARI, TIBBİ CİHAZ DEZENFEKTANLARI VE MEDİKAL CİHAZLAR İÇİN STERİL
BUĞU ÖNLEYİCİ SOLÜSYON, STERİL VE STERİL OLMAYAN KAYGANLAŞTIRICI JELLER, DOĞUM
JELLERİ, STERİL VE STERİL OLMAYAN ULTRASON JELLERİ, STERİL VE STERİL OLMAYAN BURUN
SOLÜSYONLARI, BİT ŞAMPUANI VE SPREYİ VE SMEAR DOKU SABİTLEYİCİ SPREYİNİN TASARIMI,
ÜRETİMİ VE SATIŞI

*MANUFACTURING AND SALES OF MEDICAL X-RAY SOLUTIONS, MEDICAL DEVICE
DISINFECTANT, STERILE ANTIFOG SOLUTION FOR MEDICAL DEVICES, STERILE AND NON-
STERILE LUBRICANT GELS, OBSTETRIC GEL, STERILE & NON-STERILE ULTRASOUND GELS,
STERILE & NON-STERILE NASAL SOLUTIONS, ANTI-LICE AND NITS SHAMPOO AND SPRAY AND
SMEAR SPRAY*

belirlenen standardın uygulanması konusunda tıbbi cihazlar için
yönetim sistemi yürürlüğe koyduğunu ve uygulamakta
olduğunu taahhüt eder./ Effective medical devices management
system and guarantee that you put in to apply

2018101013284-01MDMS Sayılı rapordaki inceleme ile/
2018101013284-01MDMS with the nr. examination report;

TS EN ISO 13485:2016

şartlarının sağlanmış olduğu kanıtlanmıştır, iş bu sertifika
yıllık ara denetimlerinin yapılması kaydıyla **08.08.2021**
tarihine kadar geçerlidir./ Its proven that requirements are provided.
This certificate is valid until **08.08.2021** with the condition
of surveillance audits done

Sertifika Kayıt No/ Certificate Registration Nr : 2018101013284-01
Sertifika Yayın Tarihi / Date of Issue : 10.10.2018
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 08.08.2021



Belgelendirme Bölümü Adına



ÖSAS Ö-41

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME ANONİM ŞİRKETİ

Adres : Sanayi Mh. Atatürk Cd. No 57/17 Güngören / İstanbul - Türkiye
Telefon: 0 212 909 35 90 - 0 312 500 00 10 www.turcert.com

Bu belge müşterinin TÜRCERT'in kurallarına ve sözleşme şartlarına uyduğu sürece geçerlidir.
This certificate is valid during the customer obeys the rules TÜRCERT procedures and agreements.



Belge Geçerlilik Sorgulama