

THE INTERNATIONAL CERTIFICATION NETWORK®

CERTIFICATE

IQNet and
DQS Medizinprodukte GmbH
hereby certify that the company

BHT Hygienetechnik GmbH

Division

Messerschmittstr. 11
86368 Gersthofen
Germany

has implemented and maintains a **Quality Management System**.

Scope:

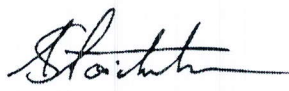
Design and development, manufacturing, sales, installation and maintenance of units and equipment for cleaning, disinfection, drying of contaminated material in hospitals, medical practices, industry and laboratories.


Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2012 + AC : 2012

Effective date	2017-07-16
Expiry date	2020-07-15
Certificate unique ID	170686045

Registration number: DE-019906 MP2012


Alex Stoichitoiu
President of IQNet


Sigrid Uhlemann
Managing Director of
DQS Medizinprodukte GmbH

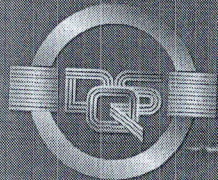
IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Certification Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland
Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia
SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey Vinçotte Belgium YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com





EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company



BHT Hygienetechnik GmbH

Division

Messerschmittstr. 11
86368 Gersthofen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Device family	Device	Class
Disinfection equipment	INNOVA Serie M2 / E2 / E2 CMS	IIb
	INNOVA Serie M2s / E2s / E2s CMS	
	INNOVA Serie M3 / E3 / E3CMS	
	INNOVA Serie M4 / E4 / E4CMS	
	INNOVA Serie M5 / E5 / E5CMS / E5CMS EFF	
	INNOVA Serie 3s	
	INNOVA Serie 4s	

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 019906 MR2
Certificate unique ID 170722750
Effective date 2018-09-22
Expiry date 2022-07-15
Frankfurt am Main 2018-09-22

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

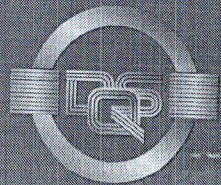
Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de



DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.





CERTIFICATE



This is to certify that the company



BHT Hygienetechnik GmbH

Division

Messerschmittstr. 11
86368 Gersthofen
Germany

Scope:

Design and development, manufacturing, sales, installation and maintenance of units and equipment for cleaning, disinfection, drying of contaminated material in hospitals, medical practices, industry and laboratories.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2012 + AC : 2012

Certificate registration no.	019906 MP2012
Certificate unique ID	170686045
Effective date	2017-07-16
Expiry date	2020-07-15
Frankfurt am Main	2017-07-12



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director



Dr. Thomas Feldmann
Head of Certification Body

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt a. M., Germany

NEW:

- Remote maintenance by online service
- 4,3" color touch screen

BHT
Disinfection Technology

INNOVA® E2s – The entry-level solution for a professional treatment

A truly reliable solution for small- and medium-sized practices

- 1 flexible endoscope or 2 ENT per cycle
- Up to 10 endoscope reprocessing cycles per day

Reliability, secure hygiene and efficiency for your endoscope reprocessing

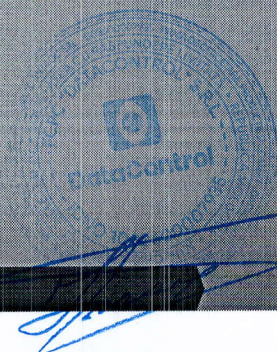
- **Reliability and ultimate cleanliness for each cycle:** compliant to DIN EN ISO 15883-1/-4 and the RKI guidelines as well as offering numerous extra features, e.g. thermal self-disinfection at 90° C in accordance with DIN EN ISO 15883-4, 4.8.1.
- **Reliability every day:** the INNOVA® E2 has been used to reprocess more than five million endoscopes in practices and hospitals worldwide.
- **Proven reliability over many years:** BHT machines – Quality engineering; there are machines still in service after 20 years or more.
- **A cost-effective investment** for a reliable practice reprocessing.
- **User friendly and efficient:** Intuitive control over 4,3" touch screen.
- **Low running costs** for chemicals, water and energy thanks to innovative construction. Key benefits: Free choice of chemicals.
- **Faster service:** Higher uptime through option of time-saving remote maintenance. Solves up to 60% of malfunctions online.



Visit our website and convince yourself:
www.bht.de

Speak to colleagues who have experience
with BHT machines.

3 HYGIENE
RELIABILITY
EFFICIENCY



How the INNOVA® E2s supports your reprocessing process



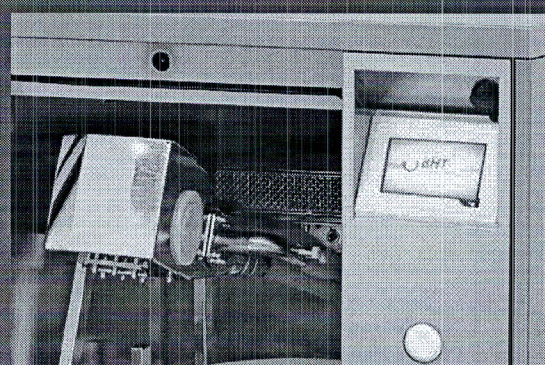
Space-saving: Perfect for any practice – with a footprint up to 40 % more compact than other machines, only 60 cm wide.



Exceptional user-friendliness and time savings: The patented BHT pressure chamber system, for example, makes connecting endoscopes much easier.

Further BHT reprocessing solution advantages

- Can be flexibly deployed alongside another E2s or E3 model to accommodate up to 30 treatments each day.
- Free choice of chemistry: Also ideal for glutaraldehyde and peracetic acid from numerous providers.
- Ideal for conventional endoscopes from Fuji, Olympus, Pentax, Storz and Wolf.
- Single channel adaption or individual channel connection or patented pressure chamber possible.
- Leak test throughout the treatment programme.
- Thermal disinfection of the rinse water in line with RKI recommendations for DH.
- Reliable documentation and traceability using batch control. User and scope are recorded by the bar-code scanner.
- Data output via printer, data logger or EDP interface. Simple integration into existing EDP systems.



- 4.3" touchpad: intuitive user interface with stepwise program explanations.
- Time-saving and convenient: Remote maintenance with BHT online service option.

INNOVA® E2s

Number of endoscopes	For 1 endoscope or 2 DH
Dimensions (W/D/H)	Built-in model: 600 x 646 x 840 mm Free-standing model: 600 x 700 x 887 mm Washing chamber: 390 x 460 x 525 mm Stainless steel base (optional): 600 x 700 x 400 mm
Hygiene concept	Hygienic workflow, 1-door
Channel connection system	Single channel connection or pressure chamber system
Single channel monitoring (CMS)	No
Chemical glutaraldehyde / peracetic acid	DH version: with boiler for glutaraldehyde DC version: filter solution for glutaraldehyde or peracetic acid
Dokumentation und Integration	Yes, interface for printer/data logger as standard. Optional scanner / EDP interface
Thermal treatment of instruments at 90° C	Also accommodates peripheral equipment
Electrical installation	1ph 230 V / 50 Hz+N+PE, Connected value: 3.61 W Fuse protection: 16 A
Water connections	DH version: cold and demineralized water; DC version: cold and demineralized water (mixed water with 30-40° C can be optionally used for acceleration); DN 20 in each case; 2.5 bar flow pressure; waste water DN 50

If you wish more information, contact our international team to advise you on the treatment solution which suits your needs best.

Tel +49 (0) 821-27893-920 • **E-Mail** sales@bht.de

BHT. Our mission: Your patients' safety

BHT Hygienetechnik GmbH • Messerschmittstr. 11 • 86368 Gersthofen • Germany • www.bht.de

