

Certificate

mdc medical device certification GmbH
certifies that



AMNOTEC International Medical GmbH
Take-off, Gewerbepark 9
78579 Neuhausen
Germany

for the scope

**development, production and distribution of
surgical and endoscopic instruments, endoscopes,
OT-lights and OT-tables**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2018-03-23
Valid until	2019-03-31
Registration no.	D1403500007
Report no.	P17-01493-108367
Stuttgart	2018-03-23

A handwritten signature in black ink, appearing to be "J. A.", is written over a light blue horizontal line.

Head of Certification Body



EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

AMNOTEK International Medical GmbH
Take-off, Gewerbepark 9
78579 Neuhausen
Germany

for the scope

**reusable surgical instruments, instruments for endoscopy, endoscopes and
instruments for high-frequency surgery
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex II – excluding Section 4
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2018-07-17
Valid until	2023-03-23
Registration no.	D1403500009
Report no.	P17-01493-125003
Stuttgart	2018-07-17



Head of Certification Body



Attachment of the certificate

No. D1403500009

Date 2018-07-17

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Product category	Product	Class	Product code	
Endoscopes	Laparoscope	Ila	12-291	
	Nephroscope	Ila	15-290	
	Rigid Endoscopes	Ila	11-274	
Instruments for endoscopy	Instruments for Cystoscopy / Urethroscopy	Ila	11-114	
	Instruments for Hysteroscopy	Ila	12-081	
	Instruments for Resectoscopy	Ila	13-335	
	Laser Fiber Guides, Endoscopic	Ila	18-097	
	Suction / Irrigation-pump Laparoscopy	Ila	17-424	
Instruments for high-frequency surgery	CO2 Insufflator Laparoscopy	Ilb	16-849	
	HF-Electrodes Bipolar coagulation electrode Bipolar coagulation forceps Bipolar dissectors Bipolar grasping forceps	Ilb	15-579	
	High-frequency instruments for endoscopy Monopolar electrode	Ilb	16-860	
	LAP forceps with HF-connection	Ilb	11-502	
	LAP scissors with HF-connection	Ilb	13-484	
	Scissors with HF-connection Bipolar scissors	Ilb	15-245	
	Suction / irrigation cannula with HF-connection	Ilb	16-860	
	reusable surgical instruments	Insufflation cannulas	Ila	12-750
		Suction and irrigation cannulas	Ila	15-206
		Trocar sleeve	Ila	15-260
Uterus manipulator		Ila	15-677	



Head of Certification Body

