

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	2019-04-30
Valid until	2023-03-23
Registration no.	D1403500012
Report no.	P18-01694-146377
Stuttgart	2019-04-30



Head of Certification Body



Attachment of the certificate

No. D1403500012

Date 2019-04-30

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Product category	Product	Class	Product code
Endoscopes	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
Instruments for high-frequency surgery	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
	HF-Electrodes Bipolar coagulation electrode Bipolar coagulation forceps Bipolar grasping forceps	Ilb	15-579
	High-frequency instruments for endoscopy Monopolar electrode	Ilb	16-860
	Suction / irrigation cannula with HF-connection	Ilb	16-860
	reusable surgical instruments	Insufflation cannulas	Ila
Suction and irrigation cannulas		Ila	15-206
Trocar sleeve		Ila	15-260



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