

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

AMNOTEK International Medical GmbH
take-off GewerbePark 11
78579 Neuhausen ob Eck
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	2021-05-17
Valid until	2023-03-23
Registration no.	D1403500015
Report no.	P20-02034-193629
Stuttgart	2021-05-17



Head of Certification Body



Attachment of the certificate

No. D1403500015

Date 2021-05-17

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Product category	Product	Class
reusable surgical instruments	Suction and irrigation cannulas	Ila
	Insufflation cannulas	Ila
	Trocar sleeves	Ila
Instruments for endoscopy	Instruments for Cystoscopy / Urethroscopy	Ila
	Instruments for Hysteroscopy	Ila
	Instruments for Resectoscopy	Ila
	Laser Fiber Guides, Endoscopic	Ila
	Instruments for Urethrotomy	Ila
	Instruments for Nephroscopy	Ila
	Instruments for Lithotripsy	Ila
Endoscopes	Rigid Endoscopes	Ila
Instruments for high-frequency surgery	Laparoscopic forceps with HF-connection	IIb
	Laparoscopic scissors with HF-connection	IIb
	Scissors with HF-connection	IIb
	Bipolar scissors	IIb
	HF-Electrodes	IIb
	Bipolar coagulation electrodes	IIb
	Bipolar coagulation forceps	IIb
	Bipolar grasping forceps	IIb
	High-frequency instruments for endoscopy	IIb
	Monopolar electrodes	IIb
	Suction / irrigation cannulas with HF-connection	IIb



Head of Certification Body