

# 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<br>Bipolar scissors   | Ilb                   | 15-245       |
|  | HF-Electrodes<br>Bipolar coagulation electrode<br>Bipolar coagulation forceps<br>Bipolar grasping forceps | Ilb                   | 15-579       |
|  | High-frequency instruments for endoscopy<br>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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