

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**H. + H. Maslanka
Chirurgische Instrumente GmbH
Stockacher Straße 172
78532 Tuttlingen
Germany**

for the scope

**Instruments for 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 | 2018-05-28 |
| Valid until | 2023-05-27 |
| Registration no. | D1038400058 |
| Report no. | P18-00304-115492 |
| Stuttgart | 2018-05-25 |



Head of Certification Body



Attachment of the certificate

No. D1038400058

Date 2018-05-25

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| Product category | Product | Class | Product code |
|-------------------------------|--|--------|--------------|
| Instruments for surgery | Aspiration needle, biopsy needle | Ila | 12-734 |
| | Aspiration needle, biopsy needle (disposable) | Ila | 12-734 |
| | Biopsy probe for the neurosurgery (disposable) | III | 12-734 |
| | Transseptale needle (disposable) | III | 12-738 |
| | Cytology brush | Ila | 15-018 |
| | Cytology brush (disposable) | Ila | 15-018 |
| | ERCP catheter, spray catheter | Ila | 15-209 |
| | ERCP catheter, spray catheter (disposable) | Ila | 15-209 |
| | Foreign body forceps, foreign body grasper, polyp grasper | Ila | 15-628 |
| | Foreign body grasper, polyp grasper (disposable) | Ila | 15-628 |
| | Flex-Pusher (position instrument for Occluder) (disposable) | III | 16-223 |
| | Biopsy forceps (disposable) | Ila | 16-268 |
| | Biopsy forceps, scissor forceps, punches | Ila | 16-268 |
| | Cardio biopsy forceps, cardio grasping forceps (disposable) | III | 16-268 |
| | Biopsy forceps, foreign body forceps, scissor forceps, punches for rigid endoscopy | Ila | 16-269 |
| | Biopsy forceps for rigid endoscopy (disposable) | Ila | 16-269 |
| | Double lumen probe | Ila | 17-569 |
| | Double lumen probe (disposable) | Ila | 17-569 |
| | Injection needle | Ila | 17-569 |
| Injection needle (disposable) | Ila | 17-569 | |



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