

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that



**BAK
Kohler Medizintechnik e. K.
Siemensring 15
78579 Neuhausen ob Eck
Germany**

for the scope

**rigid endoscopes and accessories, instruments for HF-surgery,
retractors, suction instruments, oscillating instruments, trocars
(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	2016-03-07
Valid until	2020-06-30
Registration no.	D1289900006
Report no.	P15-00622-68851
Stuttgart	2016-03-07

A handwritten signature in blue ink, appearing to be 'HLC', is written over a light blue rectangular background.

Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

Attachment of the certificate

No. D1289900006

Date 2016-03-07

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Product category	Product	Classes	Product code
Instruments for HF-surgery	Electrode, electrosurgical	IIb	11-499
	Forceps electrosurgical, general-purpose	IIb	11-502
Oscillating instruments	Blades saw, orthopedic (single-use and reusable)	IIa	13-447
Retractors	Retractor, abdominal	IIa	13-375
	Retractor, self-retaining	IIa	13-390
	Spreader, rib	IIa	13-709
	Spreader, other	IIa	15-253
Rigid endoscopes and accessories	Arthroscope	IIa	10-198
	Endoscope, rigid	IIa	11-274
	Hysteroscope	IIa	12-081
	Laparoscope	IIa	12-291
	Otoscope	IIa	12-849
	Pharyngoscope	IIa	13-011
	Thoracoscope	IIa	14-047
	Bronchoscope, rigid	IIa	15-074
	Laryngoscope, rigid	IIa	15-076
	Ureteroscope	IIa	15-788
	Obturator, endoscopic	IIa	16-155
	Cystoscope, rigid	IIa	17-145
Suction instruments	Cannula, aspirating	IIa	10-566
	Cannula, sinus	IIa	10-578
	Needle, cholangiographic	IIa	12-739
	Needle, pneumoperitoneal	IIa	12-750
	Suction and irrigation cannulas	IIa	15-206
	Cannula, miscellaneous		
	Punch, miscellaneous	IIa	15-239
	Cannula, suprapubic	IIa	16-420
	Suction tip, general purpose	IIa	16-883
Cannula, liposuction	IIa	17-640	
Trocars	Trocar, thoracic	IIa	14-161
	Trocar, miscellaneous	IIa	15-260



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