



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

## Tontarra Medizintechnik GmbH

Daimlerstraße 15  
78573 Wurmlingen  
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

### Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Sterilizable non-active surgical instruments and optics as well as active surgical instruments according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	448891 MR2
Certificate unique ID	170775468
Effective date	2021-03-11
Expiry date	2024-05-26
Frankfurt am Main	2021-03-11

### DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



## Annex to certificate

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## Tontarra Medizintechnik GmbH

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Device family	Device	Class
Endoscopic Instruments	Arthroscopy sheaths	IIa
	Hysteroscopy sheaths	
	Nephroscopy sheaths	
	Resectoscopy sheaths	
	Cystoscopy sheaths	
	Urethrotome sheaths	
	Resectoscopy working elements	
Monopolar and bipolar Instruments	Dismantable monopolar and bipolar coagulation forceps for MIS	IIb
	Endo-Cut disposable tips, sterile	
	Bipolar scissors	IIb
	Bipolar forceps for MIS	IIb
	Monopolar and bipolar coagulation tweezers	IIb
Optics	Cholangiography forceps, sterile	IIa
	Arthroscope	IIa
	Hysteroscope	IIa
	Cystoscope	IIa
	Laparoscope	IIa
	Nephroscope	IIa
	Ureterorenoscope	IIa
	Ventrikuloscope	IIa
	Otoscope	IIa
Endoscopic instruments and accessoires	Laryngoscope, starr	IIa
	Trocar sleeves	IIa
Electrodes	Verres needles	IIa
	Monopolar RF electrodes	IIb
	Bipolar RF electrodes	IIb
	Sterile resectoscopy electrodes	IIb



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Device family	Device	Class
Suction cannulas	Monopolar suction cannulas for MIS	I Ib
Suction / irrigation instruments	Suction / irrigation instruments	I Ia
Retractors	Retractors, self-retaining	I Ia