



EC-CERTIFICATE

(Full quality assurance system)

DQS Medizinprodukte GmbH

hereby certifies that the company

Axtrocare GmbH

Wiesenstraße 1
78166 Donaueschingen
Germany

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

An audit, documented in a report, performed by DQS, has verified that this quality assurance system fulfils the requirements of

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

with respect to the following medical devices:

Instruments and Devices for Endoscopy, Surgical, Orthopedy, Traumatology as listed in annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body 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. In case of class I devices the certificate is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. In case of class II devices the certificate is restricted to the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate registration No.	423399 MR2
Certificate unique ID	170516627
Effective date	2011-07-08
Expiry date	2016-07-07
Frankfurt am Main	2011-07-08

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



Annex to Certificate
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Axtrocare GmbH

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Product Category	Product	Class
Endoscopy and Surgical	Trokar sleeves and Cannulas, Optics, Endoscopy Devices	Ila
	Uterine-Cannulae, Sinus-Cannulae, Urology-Cannulae, Neuroscopy-Cannulae, Suction-Irrigation-Cannulae, other Cannulae, other Trocars, Lavage Units, Pneumoperitoneal Needles, Uterine Elevators, Fittings/Adapters, Luer, Elevators, Surgery electrodes holder, Morcellator Drivers, sterile Morcellator Knives, sterile Morcellator-Valve, Cystoscopes (rigid), Arthroscopes, Laparoscopes, Hysteroscopes	Ila
	Electrosurgical instruments	Ilb
	Lap-Instruments and Forceps HF Active Electrosurgical Electrodes	Ilb
Orthopaedey and Traumatology	Instruments, Drill bits, Cutters, Devices	Ila
	Arthroscopic Shaver Systems	Ila
	sterile Meniscus Cutters	Ila
	Orthopaedic Prosthesis Implantation Instruments	Ila