



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

A.M.I. Agency for Medical Innovations GmbH

Im Letten 1
6800 Feldkirch
Austria

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:

Medical devices for surgery and diagnostics, implants 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.	066924 MR2
Certificate unique ID	170771703
Effective date	2020-09-14
Expiry date	2024-05-26
Frankfurt am Main	2020-09-14

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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Device family	Device	Class
Coloproctology	Haemorrhoidal treatment devices, consumables, instruments & accessories	Ila, Is
	Anal fistula treatment devices & instruments	Ila, IIb
	Faecal incontinence treatment implants & accessories	IIb
	Auxiliary devices & instruments for coloproctological surgery	Is
Oncology	Infusion ports & accessories	Ila
	A.M.I.® Infusion Port System	III
Laparoscopy	Hernia treatment implants, devices & accessories	IIb
	Tissue extraction devices & accessories	Ila
	Laparoscopic instruments, HF instruments, consumables & accessories	Ila, IIb
	Trocars & accessories	Ila
	Tissue retraction devices & accessories	Ila
Suture instruments, consumables & accessories	Ila	
Morbid Obesity	Morbid obesity treatment implants, instruments & accessories	Ila, IIb
Gynaecology/ Urogynaecology	Tissue extraction & containment devices & accessories	Ila
	Implants, instruments & accessories for female urinary incontinence treatment	IIb
	Implants, instruments & accessories for pelvic floor reconstruction	IIb
	Suture instruments, consumables & accessories	IIb
	A.M.I.® Urogynaecology Instruments	III
Urology	Implants, instruments & accessories for male urinary incontinence treatment & accessories	IIb