



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	170619076
Effective date	2015-06-13
Expiry date	2020-06-12
Frankfurt am Main	2015-06-13

DQS Medizinprodukte GmbH

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Head of Certification Body

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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	A.M.I. [®] HAL / RAR [®] System	Ila
	A.M.I. [®] Soft Anal Band System	Ilb
	A.M.I. [®] Fistula Drainage System	Ilb
Oncology	A.M.I. [®] Infusion Port System	III
Laparoscopy	A.M.I. [®] -dock System	Ila
	A.M.I. [®] Mesh Implants	Ilb
	A.M.I. [®] Disposable Instruments	Is / Ila
	A.M.I. [®] TissueBag System	Ila
	A.M.I. [®] Easy Instrument System	Ilb
	A.M.I. [®] TIC System	Ila / III
	A.M.I. [®] Port System	Ila
	A.M.I. [®] EndoSAIL System	Is / Ila
A.M.I. [®] Flexible XS	Ila	
Morbid Obesity	A.M.I. [®] Gastric Band System	Ilb
	A.M.I. [®] Finger Disposable Instruments	Ila
	A.M.I. [®] Safety Port	Ilb
Urogynaecology	A.M.I. [®] Urinary Incontinence Treatment System	Ilb
	A.M.I. [®] Anatomic Pelvic Floor Repair System	Ilb
	A.M.I. [®] Urogynaecology Instruments	Ila / Ilb / III