



EC-CERTIFICATE

(Full quality assurance system)

DQS Medizinprodukte GmbH

hereby certifies that the company

A.M.I. Agency for Medical Innovations GmbH

Im Letten 1
6800 Feldkirch
Österreich

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:

Medical devices for surgery and diagnostics, implants

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 Is devices the certificate is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. In case of class Im devices the certificate is restricted to the aspects of manufacture concerned with the conformity of the products with metrological requirements.

| | |
|------------------------------|------------|
| Certificate registration No. | 066924 MR2 |
| Certificate unique ID | 170530317 |
| Effective date | 2011-08-30 |
| Expiry date | 2012-07-19 |
| Frankfurt am Main | 2011-08-30 |

Frank Graichen
Managing Director

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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 Notified Body Number 0297.



Annex to Certificate
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| Product Groups | Product Family | Class |
|--------------------------|---------------------------------------------|--------------|
| COLOPROCTOLOGY | A.M.I.® HAL System | IIa |
| | A.M.I.® RAR System | IIa |
| | A.M.I.® Soft Anal Band System | IIb |
| INFUSION PORT SYSTEMS | A.M.I.® Infusion Port System | III |
| LAPAROSCOPY | A.M.I.® -dock System | IIa |
| | A.M.I.® Mesh Implants | IIb |
| | A.M.I.® Disposable Instruments | IIa, III |
| | A.M.I.® TissueBag System | IIa |
| | A.M.I.® SituClean Device | IIa |
| | A.M.I.® OptiClean Device | IIa |
| | A.M.I.® Easy Instrument System | IIb |
| | A.M.I.® TIC System | IIa, III |
| | A.M.I.® Port System | IIa |
| | A.M.I.® EndoSAIL System | IIa, Is |
| | A.M.I.® Endo GEM System | Is |
| A.M.I.® Intro GEM System | IIa | |
| MORBID OBESITY | A.M.I.® Soft Gastric Band System | IIb |
| | A.M.I.® Finger Disposable Instruments | IIa |
| | A.M.I.® Safety Port System | IIb |
| TRAUMATOLOGY | A.M.I.® Drill Wires & Drill Nails | IIa |
| UROGYNAECOLOGY | A.M.I.® TVA / TOA System | IIb |
| | A.M.I.® Urocell Sonoject | IIa |
| | A.M.I.® Anatomic Pelvic Floor Repair System | IIb |
| | A.M.I.® ATOMS System | IIb |
| | A.M.I.® i-stitch System | IIb, III |
| | A.M.I.® UroSeal | IIb |