EU Quality Management Certificate

This is to certify that the company

A.M.I. Agency for Medical Innovations GmbH

Im Letten 1
6800 Feldkirch
Austria

SRN: AT-MF-000016792

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	066924 MDR2017Q
Certificate ID	1000163685
Effective date	2024-02-01
Expiry date	2028-09-26
Frankfurt am Main,	2024-02-01

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

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Head of Certification Body
(non-active medical devices)

Annex to EU Quality Management Certificate
SRN of Manufacturer: AT-MF-000016792
Certificate ID: 1000163685

Device categories and variants covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	AHK 007-A.M.I. HAL Knotpusher
Risk classification:	Class Ir
Basic-UDI-DI:	EAMIA34B9C1D1N8
Intended purpose:	Reusable knot pusher for placing knots during hemorrhoidal artery ligation. Part of the A.M.I HAL-RAR System.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	K6601-disposable Knotpusher
Risk classification:	Class Is
Basic-UDI-DI:	EAMIA45B3C1D2MC
Intended purpose:	Disposable knot pusher for accurate placement of the suture knot during hemorrhoidal artery ligation. Part of the A.M.I. HAL-RAR System.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	RAR2081-RAR Flexi Probe
Risk classification:	Class IIa
Basic-UDI-DI:	EAMIA45B4C1D2MP
Intended purpose:	Single-use probe with sleeve for a variable opening window during detection, ligation and mucopexy of hemorrhoidal arteries. Part of the A.M.I. HAL / RAR System.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	IST1010 - i-Stitch
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMIIST10100
Intended purpose:	Reusable instrument for suture attachment to tissue with or without surgical mesh implants in urogynaecology. To be used with i-Stitch loading units.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	IST1040 - i-Stitch up
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMIIST10400
Intended purpose:	Reusable instrument for suture attachment to tissue with or without surgical mesh implants in urogynaecology. To be used with i-Stitch loading units.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	IGY-BAR - InGYNious Bar
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMIIGY-BAR0
Intended purpose:	Device for structured suture pre-positioning used in combination with the InGYNious mesh implants.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	ATS5010 - ATOMS Tunneller
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMIATS50100
Intended purpose:	Reusable instrument for the placement of the ATOMS implant.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TOA5130 - A.M.I. TOA Tunneller
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMITOA51300
Intended purpose:	The Tunnellers are intended for the placement of A.M.I. urogynaecological and urological mesh implants.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TOA5140 - A.M.I. TOA Tunneller Universal
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMITOA51400
Intended purpose:	The Tunnellers are intended for the placement of A.M.I. urogynaecological and urological mesh implants.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TVA5030 - A.M.I. TVA Tunneller
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMITVA50300
Intended purpose:	The Tunnellers are intended for the placement of A.M.I. urogynaecological and urological mesh implants.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	OA5170 - A.M.I. TOA Tunneller Slimline
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMITOA51700
Intended purpose:	The Tunnellers are intended for the placement of A.M.I. urogynaecological and urological mesh implants.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TOA5180 - A.M.I. TOA Tunneller Universal Slimline
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMITOA51800
Intended purpose:	The Tunnellers are intended for the placement of A.M.I. urogynaecological and urological mesh implants.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TVA5040 - A.M.I. TVA Tunneller Slimline
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMITVA50400
Intended purpose:	The Tunnellers are intended for the placement of A.M.I. urogynaecological and urological mesh implants.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	AHN 006 - A.M.I. HAL Needleholder
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMIAHN0060
Intended purpose:	Reusable needle holder for use during hemorrhoidal artery ligation. Part of the A.M.I HAL-RAR System.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TRI2010 - Wi-3 HAL-RAR Unit
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMITRI20700
Intended purpose:	Reusable accessory to comfortably hold the Wi-3 HAL-RAR system in position.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	CDS2010 - Comfort Drain Grasper
Risk classification:	Class Ir
Basic-UDI-DI:	+EAMICDS20100
Intended purpose:	Device to assist the closure of the Comfort Drain during implantation.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TBI1011 - A.M.I. TissueBag Premium
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMITBI10110
Intended purpose:	The products of the A.M.I. TissueBag System are used for the safe removal of specimen (appendix, gallbladder, myoma, cysts etc.) during laparoscopic procedures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TBI1031 - A.M.I. TissueBag Premium 5 mm
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMITBI10310
Intended purpose:	The products of the A.M.I. TissueBag System are used for the safe removal of specimen (appendix, gallbladder, myoma, cysts etc.) during laparoscopic procedures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	MCS5111 - More-Cell-Safe
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMIMCS51111
Intended purpose:	More-Cell-Safe is intended for use as a tissue containment system during minimally invasive gynecologic surgery to enable the isolation and containment of tissue considered benign, resected during multi-site laparoscopic surgery for power morcellation and removal.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	MCS5151 - More-Cell-Safe 30
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMIMCS51511
Intended purpose:	More-Cell-Safe is intended for use as a tissue containment system during minimally invasive gynecologic surgery to enable the isolation and containment of tissue considered benign, resected during multi-site laparoscopic surgery for power morcellation and removal.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	MCS5131 - More-Cell Bag
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMIMCS51311
Intended purpose:	More-Cell-Safe is intended for use as a tissue containment system during minimally invasive gynecologic surgery to enable the isolation and containment of tissue considered benign, resected during multi-site laparoscopic surgery for power morcellation and removal.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	FIX2001 - FiXcision
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMIFIX20011
Intended purpose:	FiXcision is intended for the excision of fistula tissue within anal fistula surgery.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	AHS 004 - A.M.I. HAL Probe Single use
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMIAHS0040
Intended purpose:	Single-use probe for detection and ligation of hemorrhoidal arteries. Part of the A.M.I. HAL / RAR System.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TRI2011 - Wi-3 Probe
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMITRI20110
Intended purpose:	Single-use probe with sleeve for a variable opening window during detection, ligation and mucopexy of hemorrhoidal arteries. Part of the A.M.I. HAL / RAR System.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	TRI2081 - Flexi Probe II
Risk classification:	Class IIa
Basic-UDI-DI:	+EAMITRI20810
Intended purpose:	Single-use probe with sleeve for a variable opening window during detection, ligation and mucopexy of hemorrhoidal arteries. Part of the A.M.I. HAL / RAR System.

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Examinations and tests performed:
066924_A210384MED_01 dated 2023-04-13
066924_A210384MED_01 K6601_Is dated 2023-04-24
066924_A210384MED_02 AHK007_1r dated 2023-06-10

Further conditions for or limitations to the validity of the certificate:
In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-09-27	170782129	Addition of the products IST1010 - i-Stitch, IST1040 - i-Stitch up, IGY-BAR - InGYNious Bar, ATS5010 - ATOMS Tunneller, TOA5130 - A.M.I. TOA Tunneller, TOA5140 - A.M.I. TOA Tunneller Universal, TVA5030 - A.M.I. TVA Tunneller, OA5170 - A.M.I. TOA Tunneller Slimline, TOA5180 - A.M.I. TOA Tunneller Universal Slimline, TVA5040 - A.M.I. TVA Tunneller Slimline, AHN 006 - A.M.I. HAL Needleholder, TRI2010 - Wi-3 HAL-RAR Unit, CDS2010 - Comfort Drain Grasper, TBI1011 - A.M.I. TissueBag Premium, TBI1031 - A.M.I. TissueBag Premium 5 mm, MCS5111 - More-Cell-Safe, MCS5151 - More-Cell-Safe 30 MCS5131 - More-Cell Bag, FIX2001 – FiXcision, AHS 004 - A.M.I. HAL Probe Single use, TRI2011 - Wi-3 Probe, TRI2081 - Flexi Probe II