DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

A.M.I. Agency for Medical Innovations GmbH

Im Letten 1

AUT – 6800 Feldkirchen

18.03.2024

Notified Body Confirmation Letter

Reference: 170774558

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

A.M.I. Agency for Medical Innovations GmbH

Im Letten 1,

6800 Feldkirch

Austria

SRN Number: AT-MF-000016792

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided

evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

i.A. Dr. Daniel Siuda
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AAB 300 - Soft Anal Band ++EAMIA1B7C1D2J8	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
PFR5711 - ProGYNious A ++EAMIA51B8C1D2MJ	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
PFR5721 - ProGYNious P ++EAMIA51B8C1D2MJ	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
PFR5731 - ProGYNious ++EAMIA51B8C1D2MJ	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297

AGB 374 - A.M.I. Soft Gastric Band Premium Standard ++EAMIA13B7C1D2KV	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
AGB 374_LP - A.M.I. Soft Gastric Band Premium Standard ++EAMIA13B7C1D2KV	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
AGB 376_LP - A.M.I. Soft Gastric Band Premium Long ++EAMIA13B7C1D2KV	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IST1011 - i-Stitch loading unit PP 0 ++EAMIA3B7C1D2KA	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IST1021 - i-Stitch loading unit PDO 2-0 ++EAMIA3B8C1D2KM	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297 Certificate 490544 MRA (Unique ID 1770764797); NB 0297
IST1031 - i-Stitch loading unit PET 0 W ++EAMIA3B7C1D2KA	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IST1051 - i-Stitch loading unit PDO 0 ++EAMIA3B8C1D2KM	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297 Certificate 490544 MRA (Unique ID 1770764797); NB 0297
PFR5641 - EndoGYNious ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
PFR5651 - PelviGYNious ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
BSC5001 - BSC Mesh ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IGY5921 - InGYNious V ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IGY5951 - InGYNious D A L ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IGY5551 - InGYNious D A L-PP ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IGY5961 - InGYNious D A S ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IGY5561 - InGYNious D A S-PP ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297

IGY5971 - InGYNious D P L ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IGY5571 - InGYNious D P L-PP ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IGY5981 - InGYNious D P S ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IGY5581 - InGYNious D P S-PP ++EAMIA4B8C1D2L6	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
ATS5031 - Tubing Plug ++EAMIA5B7C1D2LC	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
ATS5041 - ATOMS ++EAMIA5B7C1D2LC	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
ATS5051 - Scrotal Port for ATOMS ++EAMIA5B7C1D2LC	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
ATS5061 - Tubing Connector ++EAMIA5B7C1D2LC	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
PFR5021 - A.M.I. Multi Purpose Sling ++EAMIA6B8C1D2M8	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
TOA5121 - A.M.I. TOA Sling ++EAMIA6B8C1D2M8	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
TVA5021 - A.M.I. TVA Sling ++EAMIA6B8C1D2M8	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
SUI5011 - sensiTVT ++EAMIA6B8C1D2M8	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
SUI5021 - sensiTVT-A ++EAMIA6B8C1D2M8	Class III	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
CDS2001 - Comfort Drain ++EAMIA37B7C1D2P7	Class IIb implantable non- WET device	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
TRI2010 - Wi-3 HAL-RAR Unit ++EAMIA34B4C1D1LH	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
ICT5011 - i-Cut ++EAMIA47B4C1D2NR	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
IST1010 - i-Stitch ++EAMIA3B9C1D1KW	Class I devices that qualify as re-usable surgical instruments	N/A	N/A

IST1040 - i-Stitch up ++EAMIA3B9C1D1KW	Class I devices that qualify as re-usable surgical instruments	N/A	N/A
IGY-BAR - InGYNious Bar ++EAMIA4B9C1D1LF	Class I devices that qualify as re-usable surgical instruments	N/A	N/A
AHK 007 - A.M.I. HAL Knotpusher ++EAMIA34B9C1D1N8	Class I devices that qualify as re-usable surgical instruments	N/A	N/A
AHN 006 - A.M.I. HAL Needleholder ++EAMIA34B9C1D1N8	Class I devices that qualify as re-usable surgical instruments	N/A	N/A
TRI2070 - Wi-3 Arm ++EAMIA34B9C1D1N8	Class I devices that qualify as re-usable surgical instruments	N/A	N/A
CDS2010 - Comfort Drain Grasper ++EAMIA37B9C1D1PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A
K6601 - disposable Knotpusher ++EAMIA45B3C1D2MC	Class I devices placed on the market in sterile condition	N/A	N/A
MCS5111 - More-Cell-Safe ++EAMIA42B4C1D2L4	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
MCS5151 - More-Cell-Safe 30 ++EAMIA42B4C1D2L4	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
MCS5131 - More-Cell Bag ++EAMIA42B4C1D2L4	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
FIX2001 - FiXcision ++EAMIA43B4C1D2LM	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
AHS 004 - A.M.I. HAL Probe Single use ++EAMIA45B4C1D2MP	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
RAR2081 - RAR Flexi Probe ++EAMIA45B4C1D2MP	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
TRI2011 - Wi-3 Probe ++EAMIA45B4C1D2MP	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297
TRI2081 - Flexi Probe II ++EAMIA45B4C1D2MP	Class IIa	N/A	Certificate 066924 MR2 (Unique ID 170774558) ; NB 0297

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
YYYY/MM/DD	XXXXXXXXX	Initial issue
YYYY/MM/DD	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list