EU Technical Documentation Assessment 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 and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	31634326 MDR2017P
Certificate ID	1000264682
Effective date	2025-10-24
Expiry date	2030-10-23
Frankfurt am Main,	2025-10-24

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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: AT-MF-000016792
Certificate ID: 1000264682

Device categories and variants covered by this certificate:

Device category:	MDN 1104 - Non-active soft tissue and other implants
Product name:	PFR Meshes Transabdominal
Models:	PFR5641 – EndoGYNious; PFR5651 – PelviGYNious
Risk classification:	III
Basic-UDI-DI:	++EAMIA4B8C1D2L6
Intended purpose:	Transabdominal mesh implant for surgical treatment of female pelvic organ prolapse (POP).

Examinations and tests performed:
066924_A209064MED_1 PFR Meshes Transabdominal dated 2025-08-16

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a