



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.	066924 MDR2017P
Certificate ID	1000257365
Effective date	2025-07-31
Expiry date	2030-07-30
Frankfurt am Main,	2025-07-31



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.



Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: AT-MF-000016792
Certificate ID: 1000257365

Device categories and variants covered by this certificate:

Device category: MDN 1104 - Non-active soft tissue and other implants
Product name: PFR Meshes, transvaginal
Models: BSC Mesh PP 0
InGYNious D A L-PP
InGYNious D A S-PP
InGYNious D P L-PP
InGYNious D P S-PP
InGYNious V
InGYNious D A L
InGYNious D A S
InGYNious D P L
InGYNious D P S
Risk classification: III
Basic-UDI-DI: ++EAMIA4B8C1D2L6
Intended purpose: Transvaginal mesh implant for surgical treatment of female pelvic organ prolapse (POP).

Examinations and tests performed:
066924_A212541MED dated 2025-06-12

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