EU Declaration of Conformity

Name and address of the manufacturer:

Dr. Arabin GmbH & Co. KG, Alfred-Herrhausen-Str. 44, 58455 Witten, Germany

We declare under our sole responsibility that the medical device

Product name	Article Code / REF Nr.	Class
Dr. Arabin Hybrid Pessary normal	AHYPN055 - 080	IIa
Dr. Arabin Hybrid Pessary normal soft	AHYPNS055 - 080	IIa

Basic UDI-DI: 426024582GYNAHYB9

SRN: DE-MF-000005474

complies with the requirements of Regulation (EU) 2017/745 and other EU Guidelines that are applicable.

Intended purpose:
The medical purpose is to use the device in case of pelvic organ prolapse grade II - III and/or stress incontinence or incompatibility with other urogynecological devices.

Indication of the risk class and the conformity assessment procedure:
Class IIa in accordance with Annex VIII of Regulation (EU) 2017/745
Conformity assessment procedure according to Annex IX Chapters I + III

Name and identification number of the Notified Body:
DNV MEDCERT GmbH
Identification number: 0482

Certificate with validity:
Certificate ID: 1340GB448241217
Valid until: 2028-07-02

This declaration of conformity is valid until the above certificate expires or if a change is made to the product.

Department	**Date:**	**Released by:**
CEO / PRRC – Prof. Dr.med. Dr.h.c.mult. B.Arabin	**02.01.2025**	B. Arabin
QM Representative – M. Prior	**02.01.2025**	Monika Prior