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
Ring Pessary	R050 - 100	IIa
Bowl Pessary	SP055 - 095	IIa
Sieve Bowl Pessary	SSP055 - 095	IIa
Urethra Pessary	UP045 - 100	IIa
Urethrabowl Pessary	USP055 - 090	IIa

Basic UDI-DI: 426024582GYNRPA5 SRN: DE-MF-000005474

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

Intended purpose for Ring Pessaries (R), Bowl Pessaries (SP) and Sieve Bowl Pessaries (SSP)
The pessaries are used to treat patients with milder forms of genital prolapse and/or stress incontinence. The treatment is indicated and monitored by the health care provider. These devices can also be used to reduce prolapse symptoms in combination with additional measures such as physiotherapy, medication, biofeedback or before and after an operation.

Intended purpose for Urethra Pessaries (UP)
The urethra pessary is used to treat patients with stress incontinence and/or milder forms of genital prolapse (possibly a cystocele). The ca-lotte (thickening on the pessary) is designed to support the transition between the bladder and urethra upwards, preventing the upper urethra from opening under stress situations such as coughing or physical stress, even reducing symptoms in mixed forms of stress and urge incontinence. The treatment is indicated and monitored by the health care provider.

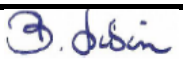
Intended purpose for Urethrabowl Pessaries (USP)
The urethra bowl pessary is used to treat patients with stress inconti-nence and/or milder forms of genital prolapse (possibly a cystocele). The calotte (thickening on the pessary) is designed to support the transition between the bladder and urethra upwards, preventing the upper ure-thra from opening under stress situations such as coughing or physical stress, even reducing symptoms in mixed forms of stress and urge incon-tinence. The treatment is indicated and monitored by the health care provider. Compared to the urethra pessary, the urethra bowl pessary slips less frequently.

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**	
QM Representative – M. Prior	**02.01.2025**