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
Urethra Pessary metal	UPM 045 – UPM 100	IIa
Hodge Pessary	HP 055 – HP 090	IIa

Basic UDI-DI: 426024582GYNMP9N SRN: DE-MF-000005474

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

Intended purpose for Urethra Pessaries metal (UPM)
The urethra pessary with metal is used to treat patients with stress incontinence 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 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 health care providers. In comparison with the urethra pessary without metal, it is preferred in elderly patients who prefer the smaller diameter due to vaginal atrophy and/or are used to this kind of device.

Intended purpose for Hodge Pessaries (HP)
When the Hodge pessary was developed, the focus was on "lifting the uterus" in case of retroflexio, an indication that has lost its significance today. The aluminum core allows individual adjustment. A Hodge pessary is now used in individual cases for the treatment of prolapse or urinary incontinence if other models cannot be tolerated (e.g., due to previous operations, preferably in older patients with deviant anatomy or narrow introitus because the shape can be adapted. It is assumed that the wearer still has (albeit reduced) pelvic floor strength. The indication is given by the treating physician. By repositioning the prolapse, it can also prevent the development of stress incontinence. The aim of treatment is to reduce the patient's prolapse symptoms, eventually in combination with additional measures.

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	**03.03.2026**	B. Arabin
QM Representative – M. Prior	**03.03.2026**	Moritz Prior