

Template

Declaration of

Conformity acc. to MDR

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Title:

Version: 1.0

Date: 20.12.2024
Created: Mo. Prior
Release: B. Arabin
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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
Cube Pessary	WPK0 - 9	lla
Cube Pessary perforated	WPLK0 - 9	lla
Tandem Pessary	TP 0+0 F0 – TP5+5 F5	lla
Tandem Pessary perforated	TPL 0+0 F0 – TP5+5 F5	lla
Club Pessary	KP050 - 090	lla

Basic UDI-DI: 426024582GYNCP8Q

SRN: DE-MF-000005474

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

<u>Indication of the risk class and the conformity assessment procedure:</u>

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	3. dibin
QM Representative – M. Prior	02.01.2025	Month Prior