

 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
Cerclage Pessary perforated	CPP 65/17/32	CPP 70/17/32	llb
	CPP 65/17/35	CPP 70/17/35	
	CPP 65/21/32	CPP 70/21/32	
	CPP 65/21/35	CPP 70/21/35	
	CPP 65/25/32	CPP 70/25/32	
	CPP 65/25/35	CPP 70/25/35	

Basic UDI-DI: 426024582OBCPP5X

SRN: DE-MF-000005474

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

Indication of the risk class and the conformity assessment procedure: Class IIb 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

<u>Certificate with validity:</u> 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. Jubin
QM Representative – M. Prior	02.01.2025	Monite Prior