



## Declaration of conformity for customized pessaries

The customized device is exclusively determined for one (cited) patient

Declaration of conformity for customized pessaries acc. to § 12 1 MPG

### To document by the company (Dr. Arabin GmbH & Co KG Witten/Berlin)

Number of order: \_\_\_\_\_

Date                                      Year                                      Month                                      Day  
\_\_\_\_\_  
\_\_\_\_\_

Material:                                      Silicone

Product and Charge specificity: \_\_\_\_\_

Risk category: \_\_\_\_\_

### To document by the physician in charge:

Physician: \_\_\_\_\_

Similarities with previous models (Type No.): \_\_\_\_\_

Proposed measurements: Length, AP \_\_\_\_\_ mm, Width \_\_\_\_\_ mm

Special support for urethra desired: YES.....NO.....

Specific anatomical demands:  
\_\_\_\_\_

**Name of patient:** \_\_\_\_\_

Date of birth: \_\_\_\_\_

Address : \_\_\_\_\_

For how long the pessary should stay? \_\_\_\_\_

Should the patient change the device herself and is she instructed? \_\_\_\_\_

We declare that the customized device fulfills the demands of paragraph I of the EU guideline 93/42 of 14-06-1993 about medical products. The documents acc. to § 7/ 5 MPV are stored and if necessary will be shown to the officials.

Data safety: Your personal data will be stored due to legal traceability acc. to MP legislation for advice and service but not be used elsewhere.

\_\_\_\_\_

Date

\_\_\_\_\_

Signature