EC declaration of conformity

In accordance with regulation 2017/745 on medical devices, Annex IX (without Chapter 2)
It is a class IIa medical device.

Product:	Pessaries for descensus genitalis/uterine prolapse and incontinence
SRN:	DE-MF-000033923
Competent Authority / Reg. no.	DE/CA22/00215449
Product and trade name (Product code):	femicare-Ring Pessary ti(R50,R55,R60,R65,R70,R75,R80,R85,R90,R95,R100) femicare-Thick Ring Pessary ti(TR50,TR55,TR60,TR65,TR70,TR75,TR80,TR85,TR90,TR95,TR100) femicare-Bowl Pessary ti(B55,B60,B65,B70,B75,B80,B85,B90,B95) femicare-Sieve Bowl Pessary ti(SB55,SB60,SB65,SB70,SB75,SB80,SB85,SB90,SB95) femicare-Urethra Pessary ti(U45,U50,U55,U60,U65,U70,U75,U80,U85,U90,U95,U100) femicare-Urethra Bowl Pessary ti(UB55,UB60,UB65,UB70,UB75,UB80,UB85,UB90) femicare-Cube Pessary ti(C25,C29,C32,C37,C41;C45,C55,C65,C70,C75) femicare-Cube Pessary perforated ti(CP25,CP29,CP32,CP37,CP41;CP45,CP55,CP65,CP70,CP75) femicare-Tandem Pessary (2 connected Cube Pessaries) ti(T)
Purpose of use:	All pessaries serve as conservative treatment of genital descensus
Basis-UDI-DI device:	426021766-T-PessariesHG
Basis-UDI-DI system:	N/A
Manufacturer:	tic Medizintechnik GmbH Endelner Feld 9 D-46286 Dorsten, Germany

We, tic Medizintechnik GmbH & Co. KG, declare under our sole responsibility that the above-mentioned medical device has been subjected to a conformity assessment procedure in accordance with Article 52 and that the product meets all applicable requirements of Regulation (EU) 2017/745 for medical devices.

The stated conformity with revision A2 is valid for all *femicare-Pessaries* placed on the market for the first time since 2026-05-14. The manufacturer manages and writes the conformance of *femicare-Pessaries* in an electronic file. The conformity stated here is valid only in conjunction with this list for the devices named therein and until the product has been changed and / or the date of expiry of the certificate(s) issued by the notified body. Identification is carried out via the LOT number / UDI.

Applied Standards:	DIN EN ISO 13485, DIN EN ISO 14971, DIN EN ISO 15223-1, DIN EN ISO 20417, DIN EN ISO 10993-1, DIN EN ISO 10993-5, DIN EN ISO 10993-6, DIN EN ISO 10993-10, DIN EN ISO 10993-11, DIN EN ISO 10993-13, DIN EN ISO 10993-18
Common Specification:	not applicable
Performed initial conformity assessment procedures and surveillance (every year)	EU 2017/745 Article 52 (6); Annex IX chapters I (establishment of QMS), III (terms of regulations) and chapter II section 4 (assessment of technical documentation). QMS Audits, Technical Documentation Assessment (Sample per category of devices), Clinical Evaluation Report updates, Post Market Clinical Follow-Up Update Report, Periodic Safety Update Report, Unannounced Audits (NB)

CE 2797

Notified body:	BSI Group, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam
MDR certification number:	MDR 740894
Dorsten, 2026-05-14	Dr Christian Kleeberg
Place / Date	Dr. Christian Kleeberg, CEO

Storage location TF: Manufacturer's company headquarters

Date of first issue: 2026-05-14