

EU Declaration of Conformity

We, **Kessel medintim GmbH**, declare our sole responsibility, that the product listed below is covered by present declaration as a **Medical Device**. The product is classified as a **Class I** device in accordance with **European Medical Device Regulation (EU) 2017/745 [MDR]** Rule 5 of Annex VIII. The product has been evaluated to Conformity Assessment Procedure of the MDR Annex II, Annex III and Article 19 and it conforms to the related General Safety and Performance Requirements of the MDR Annex I.

Additionally, we declare that the product meets all limitations for restricted substances in homogeneous materials in accordance with the latest delegated directive **2015/863/EU**.

Trade Name	Prefert® Vaginal Gel
Article No.	See Appendix Part 2
UMDNS No.:	12-401
Basis-UDI-DI	4013273PREFERTQG
Manufacturer	KESSEL medintim GmbH
Manufacturer address	Kelsterbacher Str.28 64546 Mörfelden-Walldorf GERMANY
Single registration number (SRN)	DE-MF-000013106
Intended purpose:	Vaginal lubricant for couples trying to conceive
EU Regulations / EU Directives	European device regulation (EU) 2017/745 [MDR]
Medical device risk class	Class I (non-sterile, non-measurement)
Notified body	not required
Conformity assessment procedure	Annex II, Annex III, Article 19
Issue date	11 August,2026

This declaration is submitted by:



Antje Becker, QMR/RA
Mörfelden-Walldorf, 11 August 2026

Appendix 2

Article No.	Description	UDI-DI	Details
GEL PREFERT8	Prefert Vaginal Gel 8x5ml DE-FR-IT-NL	4013273002172	Package with 8 disposal applicators of 5ml gel and instructions for use in the language version DE-FR-IT-NL
GEL PREFERT8 E	Prefert Vaginal Gel 8x5ml PL-CS-SK-SL	4013273002264	Package with 8 disposal applicators of 5ml gel and instructions for use in the language version PL-CS-SK-SL
GEL PREFERT8 ME	Prefert Vaginal Gel 8x5ml EN-EL-TR-AR	4013273002271	Package with 8 disposal applicators of 5ml gel and instructions for use in the language version EN-EL-TR-AR
GEL PREFERT8 N	Prefert Vaginal Gel 8x5ml DA-FI-NO-SV	4013273002257	Package with 8 disposal applicators of 5ml gel and instructions for use in the language version DA-FI-NO-SV
GEL PREFERT8 S	Prefert Vaginal Gel 8x5ml EN-ES-PT-HE	4013273002295	Package with 8 disposal applicators of 5ml gel and instructions for use in the language version EN-ES-PT-HE
GEL PREFERT8 SE	Prefert Vaginal Gel 8x5ml RO-BG-HU-ZH	4013273002288	Package with 8 disposal applicators of 5ml gel and instructions for use in the language version RO-BG-HU-ZH
GEL PREFERT3	Prefert Vaginal Gel 3x5ml EN-AR	4013273002783	Package with 3 disposal applicators of 5ml gel and instructions for use in the language version EN-AR