EU Declaration of Conformity [EN]

Medintim

Manufacturer	KESSEL medintim GmbH Kelsterbacher Str.28 64546 Mörfelden-Walldorf Germany SRN: DE-MF-000013106
Product Group	Gel for use with diaphragms (contraception)
Risk Class	IIb according to Annex VIII of Regulation (EU) 2017/745
Basic UDI-DI	4013273DIAGELDK
Product	See Annex
Notified Body	mdc – medical device certification GmbH Kriegerstraße 6 70191 Stuttgart Germany
ID Number	0483
Certificate Registration Number	D1141600019

We hereby declare, under our full responsibility, that the Diaphragm Gel (see Annex) comply with the general safety and performance requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 2017 on medical devices.

The conformity assessment procedure in accordance with Annex IX, Chapters I and III, has been completed and the technical documentation has been made available.
This EC Declaration of Conformity is issued under the full responsibility of the manufacturer, KESSEL medintim GmbH.

The conformity assessment procedure in accordance with Annex IX of Regulation (EU) 2017/745 is subject to the supervision of the Notified Body mdc - medical certification GmbH.
This Declaration of Conformity applies to all product units delivered from the release date specified below. The period of validity corresponds to the term of the Notified Body's authorization, unless it is replaced by a newer version beforehand.

This Declaration of Conformity is valid from 2026-06-08 to 2028-05-14

Mörfelden-Walldorf, 2026-06-08

Martin Kessel
Managing Director, PRRC

Antje Becker
Quality Management Representative

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Annex to Declaration of Conformity dated 2026-06-08

Product Group **Gel for use with diaphragms (contraception)**

Products	Art.-No.	UDI
Caya® Diaphragm Gel	DIA CAYAGEL	4013273001250
Caya® Diaphragm Gel "Niger"	DIA CAYAGEL NIGER	4013273001878
Caya® Diaphragm Gel "Nigeria"	DIA CAYAGEL NIGERIA	4013273002189
Caya® Diaphragm Gel "Benin"	DIA CAYAGEL BENIN	4013273000284