For electronic distribution only
Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

KESSEL medintim GmbH
Kelsterbacher Straße 28
64546 Mörfelden-Walldorf
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2025-09-15	Registration No.	D1141600025
Valid until	2028-05-14	Report No.	P23-01169-277768

Stuttgart, 2025-09-15

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Lubricant gel for diaphragms: Caya® Diaphragm Gel, Contragel® Grün, Green, Vert, Groen, Verde
Anadalan® Caya Gel para diaphragma

Intended purpose: Gel for use with diaphragms (contraception)

Risk class: IIb

Active3 Erection System

Risk class: IIa

The certificate is based on the previous certificate

D1141600019 (2023-05-15)

with the following changes to D1141600019:
Supplemented by the product: Active 3 Erection System