

EU Declaration of Conformity [EN]

Manufacturer	KESSEL medintim GmbH Kelsterbacher Str. 28 64546 Mörfelden-Walldorf Germany SRN: DE-MF-000013106
Product group	Vacuum Erection Device for erectile dysfunction
Intended use	Vacuum Erection Device for erectile dysfunction (ED)
Risk class	Ila in accordance with Rule 9, Annex VIII of Regulation (EU) 2017/745
UDI-DI basis	4013273AES3QJ
Product	Active 3 Erection System
Notified body	mdc – medical device certification GmbH Kriegerstraße 6 70191 Stuttgart Germany
Identification number of notified body	0483
Registration No. Certificate	D1141600025

We hereby declare under our full responsibility that the Active3 Erection System medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

The conformity assessment procedure in accordance with Annex IX, Chapter I and Chapter III has been carried out 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 surveillance of the Notified Body mdc – medical certification GmbH.

This declaration of conformity is valid to all product units delivered from the release date specified below. The period of validity corresponds to the term of the Notified Body's approval, unless it is replaced by a newer edition beforehand.

This declaration of conformity is valid

from 15 September 2025 to 14 May 2028

Mörfelden-Walldorf, December 23, 2025



Antje Becker
QMR/ Manager RA, Deputy PRRC