

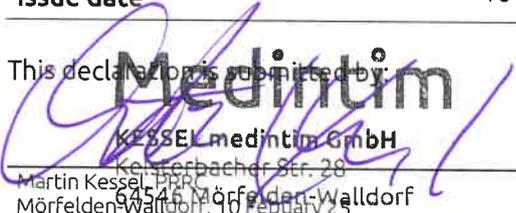
## EU Declaration of Conformity

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 1 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**.

<b>Trade Name</b>	<b>Manual Erection System</b>
<b>Article No.</b>	MES 01
<b>UMDNS No.:</b>	17-744
<b>Basis-UDI-DI</b>	<b>4013273MESREHM9</b>
<b>Manufacturer</b>	KESSEL medintim GmbH
<b>Manufacturer address</b>	Kelsterbacher Str.28 64546 Mörfelden-Walldorf GERMANY
<b>Single registration number (SRN)</b>	DE-MF-000013106
<b>Intended purpose:</b>	Manual Vacuum Erection Device for erectile dysfunction
<b>EU Regulations / EU Directives</b>	European device regulation (EU) 2017/745 [MDR]
<b>Medical device risk class</b>	Class I (non-sterile, non-measurement)
<b>Notified body</b>	not required
<b>Conformity assessment procedure</b>	Annex II, Annex III, Article 19
<b>Issue date</b>	10 February,25

This declaration is submitted by:

  
**KESSEL medintim GmbH**  
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 Germany