Medintim

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 13 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	**REHABI PVT® Peniler Vakuum Trainer**
Article No.	REHABI PVT
UMDNS Nr.:	17-744
Basis-UDI-DI	4013273MESREHM9
Manufacturer	KESSEL medintim GmbH
Manufacturer address	Kelsterbacher Str.28 64546 Mörfelden-Walldorf GERMANY
Single registration number (SRN)	DE-MF-000013106
Intended purpose:	Penile Vacuum Trainer - after prostatectomy - tissue training for IPP/Peyronie's disease
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	20 October, 25

This declaration is submitted by:

Martin Kessel, CEO
Mörfelden-Walldorf, 20.10.2025