EU Declaration of Conformity

Medintim

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.

Trade Name	**Constriction rings**
Article No.	See appendix, Part 2 – article list
UMDNS No.:	14-072
Basis-UDI-DI	**4013273AESRINGJ4**
Manufacturer	KESSEL medintim GmbH
Manufacturer address	Kelsterbacher Str.28 64546 Mörfelden-Walldorf GERMANY
Single registration number (SRN)	DE-MF-000013106
Intended purpose:	Constriction rings for vacuum devices for erectile dysfunction
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	10 Febuary,25

This declaration is submitted by:

Medintim
KESSEL medintim GmbH
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64546 Mörfelden-Walldorf
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Martin Kessel, PRRC
Mörfelden-Walldorf, 10 Febuary,25

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IBAN: DE13 5019 0000 4201 5112 46
Amtsgericht Darmstadt HRB 54267
USt-IdNr.: DE 812 260 688

Certified according ISO 13485:2021

Medintim

Annex Part 2 – Article list

Article No.	Description	UDI-DI
Ring 1	Constriction ring size 9mm	4013273000208
Ring 2	Constriction ring size 12mm	4013273000215
Ring 3	Constriction ring size 15mm	4013273000222
Ring 4	Constriction ring size 18mm	4013273000239
Ring 5	Constriction ring size 21mm	4013273000246

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