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Cod. Mecc.: PR 017790
Cod. Destinatario: KRRH6B9

EU DECLARATION OF CONFORMITY
According to the Annex IV of EU. REG. 2017/745

CE

The undersigned **For.me.sa. S.r.l.,**
with location in Via Canvelli 6, 43015 Noceto (PR), SRN NUMBER: IT-MF-000027301,
manufacturer of the following Medical Devices, **DECLARES,** under its own responsibility that the Devices listed in the table below satisfy the General Requirements of Performance and Safety reported in the Annex I of EU. REG. 2017/745.

CODE	PRODUCT DESCRIPTION	BASIC UDI-DI
70-544	PUMP FOR INVALID RING	805506076PMPL2

For this purpose, For.me.sa. S.r.l. guarantees and declares under his own and sole responsibility as follows:

1. The considered device is intended as an accessory used to pump the invalid ring.
2. The considered device belongs to **Class I not sterile**, according to Rule 1 included in the **Annex VIII** of EU. REG. 2017/745;
3. The considered device is not a measuring instrument and is not intended for clinical investigation
4. This device is sold in NON STERILE package.
5. The conformity assessment procedure is based on Annexes II and III of EU. REG. 2017/745
6. For.me.sa. has a Quality Management System in agreement with the UNI CEI EN ISO 13485:2021 norm and certified by IMQ Notified Body, located in via Quintiliano n. 43, 20138 Milano (MI).
7. It is not allowed to use the above-mentioned Device for any purposes other than the intended use indicated by For.me.sa. S.r.l.
8. All documentation proving the conformity to the REG. EU 2017/745 will be made available to the relevant authorities for ten (10) years starting from the last date of production of the Device under discussion.

Noceto,23.11.2022

For.me.sa. Legal Representative
BIZZI DESOLINA

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