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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 NUMER: 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
70-508.01	INVALID RING- TEAM DELUX WITHOUT PUMP D.35	805506076CGADLX6V
70-508.02	INVALID RING- TEAM DELUX WITHOUT PUMP D.40	
70-508.03	INVALID RING- TEAM DELUX WITHOUT PUMP D.43	
70-508.04	INVALID RING- TEAM DELUX WITHOUT PUMP D.45	

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

1. The considered devices are intended to relieve bedridden patents or people just had surgical operation.
2. The considered devices belong to **Class I not sterile**, according to Rule 1 included in the **Annex VIII** of EU. REG. 2017/745;
3. The considered devices are not measuring instruments and are not intended for clinical investigation.
4. These devices are 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 Devices 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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