

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



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 |
|-------------|----------------------------------|------------------|
| FOR.005.001 | ENEMA IRRIGATOR WITH ACCESSORIES | 805506076ENTCLAK |
| FOR.005.002 | TUBE FOR ENEMA IRRIGATOR | |
| FOR.005.004 | ENEMA SPARE SET OF THREE PIECES | |
| FOR.005.005 | VAGINAL CANNULA | |

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 release the last part of the intestines of feces and/or gas using therapeutic fluids as prescribed by the attending physician, equipped with anal cannula for enemas and vaginal irrigation cannula.
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, 02/12/.2022

**For.me.sa. Legal Representative
BIZZI DESOLINA**

