GIMA S.p.A.
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ITALIAN DIVISION
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EXPORT DIVISION
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EU DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A. (single registration number (SRN): IT-MF-000011004), with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milan, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Product and trade name	Product code	Basic UDI-DI	Intended purpose	Rule
SET OF 14 HEGAR DILATORS - chrome plated	26817	8023279L0509020200000009F	To dilate the cervical canal after its insertion through the cervical os	5
SIMS RETRACTOR SET	26884	8023279L0509020200000009F	to mechanically enlarge the vagina during examination, treatment, and/or during surgical procedures	5

risk class I (not sterile), in accordance with the rules set out in Annex VIII of the Regulation (EU) 2017/745 (MDR), declares, under its sole responsibility, that this device:

- complies with the Regulation (EU) 2017/745 (MDR);
- Common Specifications have not been used for the compliance of the above medical device.

Gessate, 09/08/2025

GIMA S.p.A.
The legal
Representative
(Nicola Manzoni)