GIMA S.p.A.
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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
SIMS HYSTEROMETER 33 cm	26804	8023279L050903990000000LY	to explore the internal depth or length of the uterus, cervix, and/or vagina	5
SIMS UTERINE CURETTE - SHARP - 8mm - 26 cm	26813	802327900L0509010000000TB	for the removal of tissue during a gynaecological procedure	5
SIMS UTERINE CURETTE - SHARP - 9mm - 26 cm	26814	802327900L0509010000000TB		
SIMS UTERINE CURETTE - SHARP - 14mm - 26 cm	26815	802327900L0509010000000TB		
MARTIN HYSTEROMETER - malleable - 30 cm	26816	80232790000L90992900000YY	to explore the internal depth or length of the uterus, cervix, and/or vagina	5
SET OF 14 HEGAR DILATORS - chrome plated	26817	8023279L0509020200000009F	To dilate the cervical canal after its insertion through the cervical os	5
UMBILICAL SCISSORS USA Model - 10.5 cm	26827	802327900L0104990000000VD	to simultaneously clamp and sever the umbilical cord immediately after birth	6
SIMS RETRACTOR SET	26884	8023279L0509020200000009F	to mechanically enlarge the vagina during examination, treatment, and/or during surgical procedures	1

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, 12/06/2025

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