



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	802327900L0311022900000Q2	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 gynecological 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	802327900L0311022900000Q2	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
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, 30/06/2026

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