

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
KOGAN ENDOSPECULUM - 24 cm	26809	80232790000U0899B0000000EB
S.S. COLLIN SPECULUM-MEDIUM	29768	802327900L0590010000000TV
S.S. CUSCO SPECULUM-SMALL	29770	802327900L0590010000000TV
S.S. CUSCO SPECULUM-MEDIUM	29771	802327900L0590010000000TV
S.S. CUSCO SPECULUM-LARGE	29772	802327900L0590010000000TV
S.S. CUSCO SPECULUM-VIRGIN	29773	802327900L0590010000000TV
AMNIOSCOPE TUBE 12x24x200 mm.	29971	8023279Z1202908562000008H
AMNIOSCOPE TUBE 16x24x200 mm.	29972	8023279Z1202908562000008H
AMNIOSCOPE TUBE 20x24x200 mm.	29973	8023279Z1202908562000008H

intended purpose: Intended for use during gynecological visits

risk class I (not sterile), in accordance with the rule 5 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, 11/11/2025

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

