GIMA S.p.A. Via Marconi, 1 20060 Gessate (MI) –Italy www.gimaitaly.com



ITALIAN 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
GOLD WIRE CUTTER - 14 cm - for soft wires 0-1 mm	26570	
GOLD WIRE CUTTER - 18 cm - tor hard wires up to 1.6 mm	26571	80232790000L90993900000ZH
GOLD WIRE CUTTER - 23 cm - tor hard wires up to 2 mm	26572	00232770000170773700000211
GOLD WIRE HOLDING - 18 cm	26575	

intended purpose: designed to cut orthopaedic wires and small diameter pins in the medical field

risk class I (not sterile), in accordance with the rule 1 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, 16/06/2025

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