



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 MAYO HEGAR NEEDLE HOLDER - 16 cm	26530	80232790000L02050000000CH
GOLD MAYO HEGAR NEEDLE HOLDER - 18 cm	26531	80232790000L02050000000CH
GOLD MAYO HEGAR NEEDLE HOLDER - 20 cm	26532	80232790000L02050000000CH
GOLD MATHIEU NEEDLE HOLDER - 14 cm	26536	80232790000L02050000000CH
GOLD MATHIEU NEEDLE HOLDER - 17 cm	26537	80232790000L02050000000CH
GOLD MATHIEU NEEDLE HOLDER - 20 cm	26538	80232790000L02050000000CH
GOLD MAYO HEGAR NEEDLE HOLDER - 14 cm	26539	80232790000L02050000000CH
GOLD WEBSTER NEEDLE HOLDER - 12.5 cm	26544	80232790000L02050000000CH
GOLD CRILE WOOD NEEDLE HOLDER - 20 cm	26545	80232790000L02050000000CH
GOLD CRILE WOOD NEEDLE HOLDER - 15 cm	26546	80232790000L02050000000CH
GOLD CRILE WOOD NEEDLE HOLDER - 18 cm	26547	80232790000L02050000000CH
GOLD OLSEN HEGAR NEEDLE HOLDER - 14 cm	26540	80232790000L02050000000CH
GOLD OLSEN HEGAR NEEDLE HOLDER - 16.5 cm	26541	80232790000L02050000000CH
GOLD OLSEN HEGAR NEEDLE HOLDER - 19 cm	26542	80232790000L02050000000CH
GOLD MAYO HEGAR NEEDLE HOLDER - 26 cm	26533	80232790000L02050000000CH
GOLD MAYO HEGAR NEEDLE HOLDER - 30 cm	26534	80232790000L02050000000CH
GOLD MAYO HEGAR NEEDLE HOLDER - 24 cm	26535	80232790000L02050000000CH
MATHIEU NEEDLE HOLDER - 16 cm	26730	80232790000L02050000000CH
MATHIEU NEEDLE HOLDER - 20 cm	26731	80232790000L02050000000CH



MAYO HEGAR NEEDLE HOLDER - 16 cm	26732	80232790000L02050000000CH
MAYO HEGAR NEEDLE HOLDER - 20 cm	26733	80232790000L02050000000CH
MATHIEU NEEDLE HOLDER - 14 cm	26741	80232790000L02050000000CH
MAYO HEGAR NEEDLE HOLDER - 14 cm	26818	80232790000L02050000000CH
MAYO HEGAR NEEDLE HOLDER - 18 cm	26819	80232790000L02050000000CH
CRILE WOOD NEEDLE HOLDER - 15 cm	26852	80232790000L02050000000CH
CRILE WOOD NEEDLE HOLDER - 18 cm	26878	80232790000L02050000000CH
CRILE WOOD NEEDLE HOLDER - 20 cm	26879	80232790000L02050000000CH
T.C. MICRO PORTE-AIGUILLE LIGNE GOLD BARRAQUER - 13 cm - bouts lisses	38600	80232790000L02050000000CH
T.C. GOLD ARRUGA NEEDLE HOLDER - straight - 16 cm - plain tips	38610	80232790000L02050000150D5
T.C. GOLD ARRUGA NEEDLE HOLDER - curved - 16 cm - plain tips	38611	80232790000L02050000150D5
GOLD GILLIES NEEDLE HOLDER - 16 cm	26548	80232790000L02050000000CH
GOLD DERF NEEDLE HOLDER - 12 cm	26549	80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER straight - 14 cm - plane tip	26550	80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER straight - 18 cm	26551	80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER curved - 14 cm - plane tip	26552	80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER straight - 14 cm - rough tip	26553	80232790000L02050000000CH
GOLD CASTROVIEJO - 13 cm	26554	80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER curved - 14 cm - rough tip	26555	80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER straight - 21 cm - rough tip	26556	80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER curved - 21 cm - rough tip	26557	80232790000L02050000000CH



Intended purpose: It is used to hold and move the needle through the tissue while stitching

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, 09/08/2025

GIMA S.p.A.

The legal Representative
(Nicola Manzoni)

A handwritten signature in black ink, appearing to read 'N. Manzoni', is written below the printed name.