



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	Intended purpose	Basic UDI-DI
GOLD MAYO HEGAR NEEDLE HOLDER - 16 cm	26530	It is used to grasp a suture needle when pushing/pulling the needle and the attached suture through the tissue while suturing	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	It is used to hold needles and cut sutures	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	It is used to hold and move the needle through the tissue while stitching	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	It is used to hold and move the needle through the tissue while stitching	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	It is used to allow suturing and cutting of suture material	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	It is used to safely hold and maneuver coarse-tipped microsurgical needles during complex procedures, facilitating precise suturing in delicate tissue	80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER straight - 21 cm - rough tip	26556		80232790000L02050000000CH
GOLD CASTROVIEJO NEEDLE HOLDER curved - 21 cm - rough tip	26557		80232790000L02050000000CH



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, 5/26/2021

GIMA S.p.A.

The legal Representative
(Nicola Manzoni)

A handwritten signature in black ink, appearing to read 'N. Manzoni', is written over a horizontal line.