GIMA S.p.A.
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www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

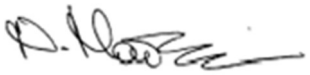
EU DECLARATION OF CONFORMITY

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
PROBE - 15 cm	26701	80232790000L90995200000XQ	intended to be used to explore cavities, wounds or fistulas during abdominal, ENT and/or orthopedic surgery	1
BUTTERFLY PROBE- 14.5 cm	26702	80232790000L90995200000XQ	Used in dissections to protect organs from the scalpel blade or scissors	1
UNNA OVAL - 14 cm	26820	80232790000L90995200000XQ	Dermal probe	6
UNNA ROUND - 14 cm	26821	80232790000V90995200010BG	Dermal probe	6
FORCEPS ROUND - 9 cm	26823	80232790OL0313990000000XR	Dermal probe	1
KATSCH - 14 cm	26825	80232790000L90995200000XQ	Dermal probe	6
GILLES HOOK - 13 cm	26826	80232790000L90995200000XQ	Dermal probe	5

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, 12/06/2025

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