GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
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
SILICONE TRAY 20x10 cm	26672	80232790000V04026000110TJ
SILICONE MAT 220x230 mm - perforated	37320	80232790000S01996000000XQ
SILICONE MAT 380x230 mm - perforated	37321	80232790000S01996000000XQ
SILICONE MAT 520x230 mm - perforated	37323	80232790000S01996000000XQ

intended pupose: support during autoclave sterilization, ensuring that the instruments do not move and are protected from contact with the container surfaces

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, 30/06/2025

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

