GIMA S.p.A.
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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
ICE BAG diameter 28 mm - large cap 6 cm	28605	80232790000M90010000000J7
ICE BAG diameter 28 mm - small cap 5 cm	28606	80232790000M90010000000J7

intended purpose: used to alleviate some symptoms and/or dysfunctions caused by diseases on the human body such as fever, hematomas, contusions, sprains, swellings

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, 20/10/2025

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