GIMA S.p.A.
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ITALIAN DIVISION
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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	UDI-DI	Basic UDI-DI
INSTANT ICE - PE bag	34111	Primary packaging (bag) 18023279341116 Secondary packaging (sales unit – carton) 08023279341119	80232790000M900100CC000UB

intended purpose: Intended to cool, for therapeutic purposes, the parts of the body on which they are applied

risk class IIa, in accordance with the rule 9 set out in Annex VIII of the Regulation (EU) 2017/745 (MDR), declares, under its sole responsibility, that this device:

- complies with general safety and performance requirements and the provisions of Regulation (EU) 2017/745;
- Common Specifications have not been used for the compliance of the above medical device;
- is manufactured in accordance with the Technical File, which satisfies the requirements set out in Annex XI, Section A of the above-mentioned Regulation, as per Certificate No. IT349382 rev. 1, issued by Bureau Veritas S.p.A. with registered office in Italy in Milan (MI) in Viale Monza n. 347, Notified Body 1370, on 27/01/2026 with expiry date 26/01/2031.

Gessate, 21/05/2026

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