



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:

Dispositivo medico Medical device	Codice/Code	Basic UDI-DI
HOT-COLD THERMY GEL 14x18 cm	28593	80232790000M9001H100000WT
HOT-COLD THERMY GEL 11x26 cm	28594	

intended to be used for the accumulation of hot/cold in thermotherapy.
Risk class I (Non-Sterile), in accordance with rule 1 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its sole responsibility, that this device:

- complies with the essential requirements and provisions of the Regulation (EU) 2017/745 (MDR), as per the Technical File archived at the company;
- no Common Specifications were used for the conformity of the aforementioned medical device;

Gessate, 26/08/2024

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.