GIMA S.p.A.
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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	Basic UDI-DI
FLACONE GEL GSK ULTRASUONI 250ml	10001	80232790000V90992800000C8
ULTRASOUND GEL - tube 250 ml - blue	33272	
ULTRASOUND GEL - tube 250 ml - transparent	33273	
ULTRASOUND GEL - tank 5 l - blue	33276	
ULTRASOUND GEL - tank 5 l - transparent	33277	
ULTRASOUND GEL - bag 5 l - blue	33286	
ULTRASOUND GEL - bag 5 l - transparent	33287	
ULTRASOUND GEL - bottle 1 l - blue	33288	
ULTRASOUND GEL - bottle 1 l - transparent	33289	

intended purpose: intended for use as conductive gels for ultrasound equipment, in all medical applications, both diagnostic and physiotherapy, where the use of ultrasound waves requires a coupling interface between the ultrasound transducer and the skin

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, 25/03/2025

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