GIMA S.p.A.
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ITALIAN DIVISION
gima@gimaitaly.com
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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
NEONATAL CRADLE with trolley	43500	80232790000V0299F4AA000NS
COVER - waterproof - for 27685	27686	80232790000V029981000005N
MATTRESS 63x37x5.5 for 43500	27685	802327900V0280998000000LF

Intended purpose: intended to accommodate newborns throughout their hospital stay and facilitate movement between departments (neonatal crib).
Accessories intended to be used together with the neonatal crib (liner and mattress).

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, 27/06/2025

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