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
PREMIUM NEWBORN CUFF + 1 TUBE TPU BLADDER	32817	80232790000C908010AA000MB
PREMIUM NEWBORN CUFF + 2 TUBE TPU BLADDER	32818	80232790000C908011AA000MQ
BOY CUFF + 1 TUBE TPU BLADDER	32880	80232790000C908010BB000MV
NIBP CHILD CUFF for BM1,BM3,BM5,BM7 needs extension cable	33736	8023279000000C9900BB000E7
PREMIUM ADULT CUFF + 1 TUBE BLADDER - royal blue	49750	80232790000C908010CC000NF
PREMIUM ADULT CUFF + 1 TUBE BLADDER - teal	49751	80232790000C908010CC000NF
PREMIUM ADULT CUFF + 1 TUBE BLADDER - ceil blue	49752	80232790000C908010CC000NF
PREMIUM ADULT CUFF + 1 TUBE BLADDER - pink	49753	80232790000C908010CC000NF

intended purpose: Intended to be applied to sphygmomanometers for measuring blood pressure

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, 04/06/2026

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