



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
INFUSION CUFF - 500 ml	32680	8023279000000B99A400000DU
ADULT VELCRO CUFF	32808	8023279000000C9910CC000FA
SPARE CUFF for Domino	32809	8023279000000C9910CC000FA
MINI CUFF 1TUBE 16 x 5 cm - premature	32810	8023279000000C9910AA000E6
MINI CUFF 1TUBE 23 x 5 cm - <3 months	32811	8023279000000C9910AA000E6
MINI CUFF 1TUBE 29 x 7 cm - 4 months to 3 years	32812	8023279000000C9910AA000E6
MINI CUFF 1TUBE 33 x 9 cm - 3-7 years	32813	8023279000000C9910BB000EQ
MINI CUFF 1TUBE 40 x 11 cm - 7-10 years	32814	8023279000000C9910BB000EQ
MINI CUFF 2TUBES 16 x 5 cm - premature	32820	8023279000000C9911AA000EK
MINI CUFF 2TUBES 23 x 5 cm - <3 months	32821	8023279000000C9911AA000EK
MINI CUFF 2TUBES 29 x 7 cm - 4 months to 3 years	32822	8023279000000C9911AA000EK
MINI CUFF 2TUBES 33 x 9 cm - 3-7 years	32823	8023279000000C9911BB000F5
MINI CUFF 2TUBES 40 x 11 cm - 7-10 years	32824	8023279000000C9911BB000F5
PEDIATRIC CUFF 16 - 22 cm for 32800-1	32825	8023279000000C9910BB000EQ
ADULT CUFF 22 - 32 cm for 32800-1 - spare	32827	8023279000000C9910CC000FA
ADULT LARGE CUFF 32 - 45 cm for 32800-1	32828	8023279000000C9910CC000FA
ADULT COTTON CUFF + BLADDER 1 TUBE	32829	8023279000000C9910CC000FA
ADULT CUFF + 1 TUBE BLADDER	32830	8023279000000C9910CC000FA
ADULT CUFF + 2 TUBES BLADDER	32832	8023279000000C9911CC000FP
OBESE CUFF + 1 TUBE BLADDER - 63 x 17.5 cm	32834	8023279000000C9910CC000FA
OBESE CUFF + 2 TUBES BLADDER - 63 x 17.5 cm	32835	8023279000000C9911CC000FP
THIGH CUFF + 1 TUBE BLADDER - 83 x 21 cm	32837	8023279000000C9921CC000G8
THIGH CUFF + 2 TUBES BLADDER - 83 x 21 cm	32838	8023279000000C9922CC000GM
PAEDIATRIC CUFF + 2 TUBES BLADDER 35x11 cm - nylon black	32839	8023279000000C9911BB000F5
OBESE CUFF + 2 TUBES BLADDER 62x17.5 cm - nylon black	32841	8023279000000C9911CC000FP
ADULT CUFF + 1 TUBE BLADDER 49x15 cm - nylon blue	32842	8023279000000C9910CC000FA
ADULT CUFF + 2 TUBES BLADDER 49x15 cm - nylon blue	32843	8023279000000C9911CC000FP
ADULT CUFF + 1 TUBE BLADDER 49x15 cm - nylon red	32844	8023279000000C9910CC000FA
ADULT CUFF + 1 TUBE BLADDER 49x15 cm - nylon black	32845	8023279000000C9910CC000FA
PAEDIATRIC CUFF + 1 TUBE BLADDER 35x11 cm - nylon	32846	8023279000000C9910CC000FA
PAEDIATRIC CUFF + 2 TUBES BLADDER 35x11 cm - nylon	32847	8023279000000C9911CC000FP
OBESE CUFF + 1 TUBE BLADDER	32848	8023279000000C9910CC000FA
OBESE CUFF + 2 TUBES BLADDER	32849	8023279000000C9911CC000FP



ADULT CUFF + 2 TUBES BLADDER 49x15 cm - nylon black	32850	8023279000000C9911CC000FP
1 TUBE BLADDER - green	32874	8023279000000C9910CC000FA
2 TUBES BLADDER - green	32875	8023279000000C9911CC000FP
INFANT CUFF + 1 TUBE TPU BLADDER	32886	8023279000000C9910AA000E6
INFANT CUFF + 2 TUBE TPU BLADDER	32887	8023279000000C9911AA000EK
CHILD CUFF + 1 TUBE TPU BLADDER	32888	8023279000000C9910BB000EQ
CHILD CUFF + 2 TUBE TPU BLADDER	32889	8023279000000C9911BB000F5
ONE PIECE THIGH CUFF + 2 TUBES	32890	8023279000000C9922CC000GM
ONE PIECE CHILDREN CUFF + 1 TUBE	32910	8023279000000C9910BB000EQ
ONE PIECE ADULT CUFF + 1 TUBE	32911	8023279000000C9910CC000FA
ONE PIECE ADULT LARGE CUFF + 1 TUBE	32912	8023279000000C9910CC000FA
ONE PIECE CHILDREN CUFF + 2 TUBES	32913	8023279000000C9911BB000F5
ONE PIECE ADULT CUFF + 2 TUBES	32914	8023279000000C9911CC000FP
ONE PIECE ADULT LARGE CUFF + 2 TUBES	32915	8023279000000C9911CC000FP
ONE PIECE THIGH CUFF + 1 TUBE	32919	8023279000000C9921CC000G8

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, 15/01/2025

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