

## 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        | 802327900000B99A400000DU  |
| ADULT VELCRO CUFF                                        | 32808        | 80232790000C908010CC000NF |
| SPARE CUFF for Domino                                    | 32809        | 80232790000C908010CC000NF |
| MINI CUFF 2TUBES 23 x 5 cm - <3 months                   | 32821        | 80232790000C908011AA000MQ |
| MINI CUFF 2TUBES 29 x 7 cm - 4 months to 3 years         | 32822        | 80232790000C908011BB000NA |
| MINI CUFF 2TUBES 33 x 9 cm - 3-7 years                   | 32823        | 80232790000C908011BB000NA |
| MINI CUFF 2TUBES 40 x 11 cm - 7-10 years                 | 32824        | 80232790000C908011BB000NA |
| PEDIATRIC CUFF 16 - 22 cm for 32800-1                    | 32825        | 8023279000000C9900BB000E7 |
| ADULT COTTON CUFF + BLADDER 1 TUBE                       | 32829        | 80232790000C908010CC000NF |
| ADULT CUFF + 1 TUBE BLADDER                              | 32830        | 80232790000C908010CC000NF |
| ADULT CUFF + 2 TUBES BLADDER                             | 32832        | 80232790000C908011CC000NU |
| OBESE CUFF + 1 TUBE BLADDER - 63 x 17.5 cm               | 32834        | 80232790000C908010CC000NF |
| OBESE CUFF + 2 TUBES BLADDER - 63 x 17.5 cm              | 32835        | 80232790000C908011CC000NU |
| THIGH CUFF + 1 TUBE BLADDER - 83 x 21 cm                 | 32837        | 80232790000C908021CC000PD |
| THIGH CUFF + 2 TUBES BLADDER - 83 x 21 cm                | 32838        | 80232790000C908022CC000PS |
| PAEDIATRIC CUFF + 2 TUBES BLADDER 35x11 cm - nylon black | 32839        | 80232790000C908011BB000NA |
| OBESE CUFF + 2 TUBES BLADDER 62x17.5 cm - nylon black    | 32841        | 80232790000C908011CC000NU |
| ADULT CUFF + 1 TUBE BLADDER 49x15 cm - nylon blue        | 32842        | 80232790000C908010CC000NF |
| ADULT CUFF + 2 TUBES BLADDER 49x15 cm - nylon blue       | 32843        | 80232790000C908011CC000NU |
| ADULT CUFF + 1 TUBE BLADDER 49x15 cm - nylon red         | 32844        | 80232790000C908010CC000NF |
| ADULT CUFF + 1 TUBE BLADDER 49x15 cm - nylon black       | 32845        | 80232790000C908010CC000NF |
| PAEDIATRIC CUFF + 1 TUBE BLADDER 35x11 cm - nylon        | 32846        | 80232790000C908010BB000MV |
| PAEDIATRIC CUFF + 2 TUBES BLADDER 35x11 cm - nylon       | 32847        | 80232790000C908011BB000NA |
| OBESE CUFF + 1 TUBE BLADDER                              | 32848        | 80232790000C908010CC000NF |
| OBESE CUFF + 2 TUBES BLADDER                             | 32849        | 80232790000C908011CC000NU |
| ADULT CUFF + 2 TUBES BLADDER 49x15 cm - nylon black      | 32850        | 80232790000C908011CC000NU |
| 2 TUBES BLADDER - green                                  | 32875        | 80232790000C908022CC000PS |
| INFANT CUFF + 1 TUBE TPU BLADDER                         | 32886        | 80232790000C908010AA000MB |
| INFANT CUFF + 2 TUBE TPU BLADDER                         | 32887        | 80232790000C908011AA000MQ |
| CHILD CUFF + 1 TUBE TPU BLADDER                          | 32888        | 80232790000C908010BB000MV |
| CHILD CUFF + 2 TUBE TPU BLADDER                          | 32889        | 80232790000C908011BB000NA |



|                                      |       |                           |
|--------------------------------------|-------|---------------------------|
| ONE PIECE THIGH CUFF + 2 TUBES       | 32890 | 80232790000C908022CC000PS |
| ONE PIECE CHILDREN CUFF + 1 TUBE     | 32910 | 80232790000C908010BB000MV |
| ONE PIECE ADULT CUFF + 1 TUBE        | 32911 | 80232790000C908010CC000NF |
| ONE PIECE ADULT LARGE CUFF + 1 TUBE  | 32912 | 80232790000C908010CC000NF |
| ONE PIECE CHILDREN CUFF + 2 TUBES    | 32913 | 80232790000C908011CC000NU |
| ONE PIECE ADULT CUFF + 2 TUBES       | 32914 | 80232790000C908011CC000NU |
| ONE PIECE ADULT LARGE CUFF + 2 TUBES | 32915 | 80232790000C908011CC000NU |
| ONE PIECE THIGH CUFF + 1 TUBE        | 32919 | 80232790000C908021CC000PD |

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)

A handwritten signature in black ink, appearing to read 'N. Manzoni', is written over a horizontal line.