

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
PLASTIC MEN URINAL	25978	802327900Y0912999900030Y3
PLASTIC BED PAN	25979	802327900Y0912998800030X5
S/S BED PAN ROUND WITH LID 320x85 mm - straigh handle	26573	802327900Y0912998800010WX
S/S BED PAN FRACTURE TYPE 418x292x85 mm with ring	26590	802327900Y0912998800010WX
S/S URINAL MALE VERTICAL diam. 114x220 mm	26591	802327900Y0912999900010XV
S/S BED PAN PERFECTION TYPE 354x289x97 mm	26593	802327900Y0912998800010WX
S/S BED FRACTURE TYPE 418x292x85 mm with tube handle	26594	802327900Y0912998800010WX
RAISED TOILET SEAT with fixing system - height 10 cm	27735	802327900Y0912150000000F8
RAISED TOILET SEAT with fixing system - height 14 cm	27737	802327900Y0912150000000F8
RAISED TOILET SEAT with fixing system - height 14 cm	27740	802327900Y0912150000000F8
RAISED TOILET SEAT with fixing system - height 10 cm	27741	802327900Y0912150000000F8
RAISED TOILET SEAT with fixed armrest - height 12,5 cm	27750	802327900Y0912150000000F8
RAISED TOILET SEAT with reclining armrest - height 12,5 cm	27751	802327900Y0912150000000F8
SAFETY GRAB BAR - 443 mm	28972	802327900Y181899B6000008G
SAFETY GRAB BAR - 545 mm	28973	802327900Y181899B6000008G
SAFETY DOUBLE GRAB BAR - 929 mm	28974	802327900Y181899B6000008G

intended purpose: Intended for use in the daily management of patients, the elderly and the disabled in hospital or home environments

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, 20/10/2025

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

