GIMA S.p.A.
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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	Rule
SILK PLASTER ROLL 10m x 2.5cm	34787	802327900M0501010000000ME	1
SILK PLASTER ROLL 10m x 5cm	34788	802327900M0501010000000ME	1
DENTAL COTTON ROLLS - 10 pack of 1000	35000	802327900Q0190040000000XR	5
SPONGE PAD - 5x5 cm - 16 plies cotton - 10 packs of 100	35005	8023279M020102010000000V5	1
SPONGE PAD - 7.5x7.5 cm - 12 plies cotton - 10 packs of 100	35006	8023279M020102010000000V5	1
SPONGE PAD - 10x10 cm - 16 plies cotton - 10 packs of 100	35007	8023279M020102010000000V5	1
SPONGE PAD - 5x5 cm - 4 plies non woven - 10 packs of 100	35010	8023279M020102010000000V5	1
SPONGE PAD - 7.5x7.5 cm - 4 plies non woven - 10 packs of 100	35011	8023279M020102010000000V5	1
SPONGE PAD - 10x10 cm - 4 plies non woven - 10 packs of 100	35012	8023279M020201010000000VD	1
GAUZE ROUND BALL diam. 15 mm - cotton	35015	8023279M020105010000000XU	5
GAUZE ROUND BALL diam. 25 mm - cotton	35016	8023279M020105010000000XU	5
GAUZE ROUND BALL diam. 50 mm - cotton	35017	8023279M020105010000000XU	5
GAUZE ROUND BALL diam. 15 mm - non woven	35020	8023279M020105010000000XU	1
GAUZE ROUND BALL diam. 25 mm - non woven	35021	8023279M020105010000000XU	1
GAUZE ROUND BALL diam. 50 mm - non woven	35022	8023279M020105010000000XU	1

intended purpose:

- PLASTER ROLL: designed to ensure the necessary hold and fixation of dressings and bandages
- Dental rolls: indicated for stopping the flow of saliva
- Gauze compresses and TNT gauze pads and cotton gauze pads: indicated for cleansing or disinfecting healthy skin
- Cotton swabs: indicated for cleansing, drying, dabbing, and applying solutions in gynecological and obstetric practices. They can be used to remove cervical mucus, staunch bleeding during minor outpatient procedures, apply disinfectant liquids to the cervix, vagina, and vulva, apply acetic acid solution or Lugol's solution, or during colposcopy.

risk class I (not sterile), in accordance with the rule 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, 17/10/2025

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