



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
SILICONE TUBE 1x3 mm - 1 mm thick	25450	80232790000V90996200110C6
SILICONE TUBE 2x4 mm - 1 mm thick	25451	80232790000V90996200110C6
SILICONE TUBE 3x5 mm - 1 mm thick	25452	80232790000V90996200110C6
SILICONE TUBE 4x6 mm - 1 mm thick	25453	80232790000V90996200110C6
SILICONE TUBE 6x8 mm - 1 mm thick	25455	80232790000V90996200110C6
SILICONE TUBE 3x6 mm - 1.5 mm thick	25458	80232790000V90996200110C6
SILICONE TUBE 4x7 mm - 1.5 mm thick	25459	80232790000V90996200110C6
SILICONE TUBE 5x8 mm - 1.5 mm thick	25460	80232790000V90996200110C6
SILICONE TUBE 6x9 mm - 1.5 mm thick	25461	80232790000V90996200110C6
SILICONE TUBE 7x10 mm - 1.5 mm thick	25462	80232790000V90996200110C6
SILICONE TUBE 4x8 mm - 2 mm thick	25466	80232790000V90996200110C6
SILICONE TUBE 5x9 mm - 2 mm thick	25467	80232790000V90996200110C6
SILICONE TUBE 6x10 mm - 2 mm thick	25468	80232790000V90996200110C6
SILICONE TUBE 8x12 mm - 2 mm thick	25469	80232790000V90996200110C6
SILICONE TUBE 10x14 mm - 2 mm thick	25470	80232790000V90996200110C6
SILICONE TUBE 5x10 mm - 2.5 mm thick	25474	80232790000V90996200110C6
SILICONE TUBE 7x12 mm - 2.5 mm thick	25475	80232790000V90996200110C6
SILICONE TUBE 8x13 mm - 2.5 mm thick	25476	80232790000V90996200110C6
SILICONE TUBE 10x15 mm - 2.5 mm thick	25477	80232790000V90996200110C6
SILICONE TUBE 6x12 mm - 3 mm thick	25480	80232790000V90996200110C6
SILICONE TUBE 7x13 mm - 3 mm thick	25481	80232790000V90996200110C6
SILICONE TUBE 8x14 mm - 3 mm thick	25482	80232790000V90996200110C6
SILICONE TUBE 9x15 mm - 3 mm thick	25483	80232790000V90996200110C6
SILICONE TUBE 10x16 mm - 3 mm thick	25484	80232790000V90996200110C6
SILICONE TUBE 12x18 mm - 3 mm thick	25485	80232790000V90996200110C6
SILICONE TUBE 8x15 mm - 3.5 mm thick	25488	80232790000V90996200110C6
SILICONE TUBE 10x20 mm - 5 mm thick	25491	80232790000V90996200110C6
MADE TO ORDER SILICONE TUBES	25495	80232790000V90996200110C6

intended purpose: intended for the pipeline of liquids or gases, but only and exclusively for EXTERNAL use

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, 26/05/2021

GIMA S.p.A.

The legal Representative
(Nicola Manzoni)