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
FRAIZER NOSE SUCTION CANNULA diameter 4 mm	26793	8023279A0601010312CC000SD
FRAIZER NOSE SUCTION CANNULA diameter 5 mm	26794	
FRAIZER NOSE SUCTION CANNULA diameter 2 mm	26795	
FRAIZER NOSE SUCTION CANNULA diameter 3 mm	26796	
ROSEN EAR SUCTION CANNULA diameter 1.5 mm	26797	
ROSEN EAR SUCTION CANNULA diameter 3 mm	26798	
NOVAK SUCTION CANNULA	26807	
SUCTION ADAPTOR with Luer tip for code 26797/8, 26807	26799	802327900L1490996700000DC

intended purpose: allow the suction or drainage of biological fluids that are not intended to be reinfused into the body

risk class I (not sterile), in accordance with the rule 5 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, 15/07/2025

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