

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	Intended purpose	Rule
KILLIAN/HARTMANN NOSE FORCEPS 75 mm, 14 cm	26764	802327900L1402020000000MP	Intended to be inserted into a nostril to maximally open the nostril by stretching the tissue around the nasal orifice, allowing access for examination or ear/nose/throat (ENT) surgical intervention	5
TIECK HALLE NOSE SPECULUM - 13.5 cm	26765	802327900L1402020000000MP		5
LUCAE HOOK fine - 14 cm	26769	8023279L140102020000000Y8	to be used to cut and grasp soft-tissue during an ear/nose/throat (ENT) procedure	1
SET HARTMANN EAR SPEC.4-5-6 mm	26770	802327900L1490040000000VS	intended to be inserted, into the ear canal to create a channel for examination, suction, irrigation, or the insertion of another surgical device during an ear/nose/throat (ENT) procedure	5
LUCAE HOOK - 14 cm	26771	8023279L140102020000000Y8	to be used to cut and grasp soft-tissue during an ear/nose/throat (ENT) procedure	1
KILLIAN NOSE FORCEPS 35 mm, 14 cm	26772	802327900L1402020000000MP	Intended to be inserted into a nostril to maximally open the nostril by stretching the tissue around the nasal orifice, allowing access for examination or ear/nose/throat (ENT) surgical intervention	5
LUCAE EAR FORCEPS 14 cm	26773	802327900L1405020000000QE	to be used to cut and grasp soft-tissue during an ear/nose/throat (ENT) procedure	5
VOLTOLINI NOSE SPECULUM adjustable - size 2	26774	802327900L1490040000000VS	Intended to be inserted into a nostril to maximally open the nostril by stretching the tissue around the nasal	5
VOLTOLINI NOSE SPECULUM adjustable - size 0	26775	802327900L1490040000000VS		5

KILLIAN NOSE FORCEPS 50 mm, 14 cm	26776	802327900L1402020000000MP	orifice, allowing access for examination or ear/nose/throat (ENT) surgical intervention	5
FIBRE OPTIC KILLIAN NOSE FORCEPS 75 mm, 14 cm	26777	802327900L1402020000000MP		5
KILLIAN NOSE FORCEPS 22 mm/14 cm	26778	802327900L1402020000000MP		5
HARTMANN EAR FORCEPS - 14 cm	26779	802327900L1405020000000QE	to be used to cut and grasp soft-tissue during an ear/nose/throat (ENT) procedure	5
HARTMANN EAR FORCEPS 9 cm	26782	802327900L1405020000000QE		5
TROELTSCH EAR FORCEPS 12 cm	26783	802327900L1405020000000QE		5
THUDICUM NOSE CLIP - Size 2	26784	8023279L03140199D600000QH	Intended to be inserted into a nostril to maximally open the nostril by stretching the tissue around the nasal orifice, allowing access for examination or ear/nose/throat (ENT) surgical intervention	5
HARTMANN EAR FORCEPS - MICRO 8 cm	26786	802327900L1405020000000QE	to be used to cut and grasp soft-tissue during an ear/nose/throat (ENT) procedure	5
HARTMANN EAR FORCEPS - MICRO 8 cm x 4mm	26787	802327900L1405020000000QE		5
MICRO EAR CUP-SHAPED POLYPUS FORCEPS	26788	802327900L1405020000000QE		5
BILLEAU LOOP - 16 cm	26790	802327900L149099020000085	Used to clean the inside of the ear canal	5
KILLIAN/HARTMANN NOSE FORCEPS 14 cm	26792	802327900L1402020000000MP	Intended to be inserted into a nostril to maximally open the nostril by stretching the tissue around the nasal orifice, allowing access for examination or ear/nose/throat (ENT) surgical intervention	5

risk class I (not sterile), in accordance with the rules 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.

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Gessate, 12/06/2025

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

A handwritten signature in black ink, appearing to read "N. Manzoni", is written below the text identifying the legal representative.