

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
COMBI SET - otoscope+torch	31300	8023279Z1214900600000002X	13
PARKER COLOUR OTOSCOPE - green	31435	8023279Z1214900600000002X	13
PARKER COLOUR OTOSCOPE - blue	31436	8023279Z1214900600000002X	13
PARKER COLOUR OTOSCOPE - yellow	31437	8023279Z1214900600000002X	13
PARKER OTOSCOPE	31440	8023279Z1214900600000002X	13
PARKER OTOSCOPE - rechargeable handle	31441	8023279Z1214900600000002X	13
SET 3 ADULT SPECULUM	31448	802327900Q03049975CC000ND	5
KIT OF 5 REUSABLE PLASTIC CANNULAS	31451	802327900U0890060000030ES	5
PARKER DIAGNOSTIC SET - bayonet	31471	802327900Z121402000000093	13
PARKER DIAGNOSTIC SET LARGE - bayonet	31473	802327900Z121402000000093	13
PARKER OPERATIVE HALOGEN OTOSCOPE	31474	8023279Z1214900600000002X	13
PARKER HALOGEN OTOSCOPE	31475	8023279Z1214900600000002X	13
PARKER HALOGEN OPHTHALMOSCOPE	31476	8023279Z121201140000000Q9	13
PARKER HALOGEN OTO-OPHTHALMOSCOPE	31477	802327900L1603033500000V5	13
XENON-HALOGEN DIAGNOSTIC SET - 3.5 V	31480	802327900Z121402000000093	13
XENON-HALOGEN OPERATIVE DIAGNOSTIC SET - 3.5 V	31482	802327900Z121402000000093	13
INFLATION BULB FOR OTOSCOPES - grey	31483	80232790000Q039935CC0009V	1
MINI EAR SPECULUM diam. 2.5 mm - grey - in dispenser	31485	802327900Q0304997500000C9	5
MINI EAR SPECULUM diam. 4 mm - grey - in dispenser	31486	802327900Q0304997500000C9	5
MINI EAR SPECULUM diam. 2.5 mm - black - in dispenser	31487	802327900Q0304997500000C9	5
MINI EAR SPECULUM diam. 4 mm - black - in dispenser	31488	802327900Q0304997500000C9	5
MINI EAR SPECULUM diameter 2.5 mm - black	31491	802327900Q0304997500000C9	5
MINI EAR SPECULUM diameter 4 mm - black	31492	802327900Q0304997500000C9	5
ADAPTOR MINI SPECULUM-PARKER OTOSCOPE	31493	80232790000Q039976000002A	1
ALLIGATOR" PEDIATRIC KIT with 100 mini speculum	31494	802327900L1603010000000QB	5
MINI EAR SPECULUM - mixed colour and diameter	31495	802327900Q0304997500000C9	5
MINI EAR SPECULUM diameter 2.5 mm - blue	31496	802327900Q0304997500000C9	5
MINI EAR SPECULUM diameter 4 mm - blue	31497	802327900Q0304997500000C9	5
MINI EAR SPECULUM diameter 2.5 mm - green	31498	802327900Q0304997500000C9	5
MINI EAR SPECULUM diameter 4 mm - green	31499	802327900Q0304997500000C9	5
SIGMA F.O. OTOSCOPE 2.5V - Xenon-halogen light - pouch - violet	31511	8023279Z1214900600000002X	13
SIGMA F.O. OTOSCOPE 2.5V - LED light - black - pouch	31513	8023279Z1214900600000002X	13
SIGMA F.O. OTOSCOPE - LED light - blue	31518	8023279Z1214900600000002X	13
GIMALUX F.O. OTOSCOPE - black	31520	8023279Z1214900600000002X	13
GIMALUX F.O. OTOSCOPE - blue	31521	8023279Z1214900600000002X	13
GIMALUX F.O. OTOSCOPE - green	31522	8023279Z1214900600000002X	13

SIGMA F.O. OTOSCOPE 2.5V - Xenon-halogen light - pouch - blue	31523	8023279Z1214900600000002X	13
SIGMA F.O. OTOSCOPE 2.5V - Xenon-halogen light - pouch - black	31524	8023279Z1214900600000002X	13
SIGMA F.O. OTOSCOPE 2.5V - Xenon-halogen light - case	31525	8023279Z1214900600000002X	13
SIGMA F.O. OTOSCOPE - LED light - black	31526	8023279Z1214900600000002X	13
SIGMA F.O. OPHTHALMOSCOPE 2.5V - Xenon-halogen - case	34352	8023279Z120210033100000PQ	13
SIGMA F.O. OTO-OPHTHALMOSCOPE SET with 2 handles - case	34354	8023279Z120210033100000PQ	13
SIGMA F.O. LED OPHTHALMOSCOPE 2.5V	31527	8023279Z121201140000000Q9	13
SIGMA F.O. OPHTHALMOSCOPE 2.5V - Xenon-halogen - pouch	31528	802327900L1603033500000V5	13
PNEUMATIC CONNECTOR PORT	31529	8023279Z121201140000000Q9	13
SIGMA F.O. OTO-OPHTHALMOSCOPE SET with 1 handle - case	31530	8023279Z121201140000000Q9	13
SIGMA F.O. LED OTO-OPHTHALMOSCOPE SET with 2 handles - case	31532	80232790000V909920000008Y	1
VISIO 2000 F.O.XENON OTOSCOPE - 3.5 V	31533	802327900L1603033500000V5	13
VISIO 2000 F.O.XENON OPHTHALMOSCOPE - 3.5 V	31536	8023279Z121201140000000Q9	13
VISIO 2000 F.O.XENON OTO-OPHTHALMOSCOPE PLUG IN - 3.5 V	31537	802327900L1603033500000V5	13
VISIO 2000 F.O.XENON OTO-OPHTHALMOSCOPE - 3.5 V	31538	802327900L1603033500000V5	13
VISIO 2000 F.O.XENON DIAGNOSTIC SET - 3.5 V	31539	802327900L1603033500000V5	13
ZOOM CHARGING STATION	31542	80232790000V90990700000AR	13
SIGMA F.O. LED OTOSCOPE 2.5V with rechargeable handle and battery - pouch - black	31580	8023279Z1214900600000002X	13
SIGMA F.O. LED OPHTHALMOSCOPE 2.5V with rechargeable handle and battery - pouch - black	31582	8023279Z121201140000000Q9	13
SIGMA F.O. LED OTO-OPHTHALMOSCOPE SET with 2 rechargeable handles - case	31584	802327900L1603033500000V5	13
CHARGING STATION for Sigma oto-ophthalmo	31586	8023279Z120210800700000UJ	13
SIGMA-C LED OTOSCOPE - black - pouch	31591	8023279Z1214900600000002X	13
SIGMA-C LED OTOSCOPE - blue - pouch	31592	8023279Z1214900600000002X	13
SIGMA-C LED OTOSCOPE - violet - pouch	31593	8023279Z1214900600000002X	13

intended purpose: Otosopes and ear specula should be used only to examine the external auditory canal and for a non-invasive general examination. The ophthalmoscope is intended for examining the material (cornea, aqueous fluid, lens, and vitreous humor) and retina of the eye.

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;

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- (for devices according to rule 13) complies with Directive 2011/65/EU (and subsequent amendments and integrations) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gessate, 31/07/2025

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

A handwritten signature in black ink, appearing to read 'N. Manzoni', is written over a horizontal line.