

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
LARYNGEAL MIRROR Number 000 - diameter 10mm	31600	802327900L1602020000000PZ	5
LARYNGEAL MIRROR Number 00 - diameter 12mm	31601	802327900L1602020000000PZ	5
LARYNGEAL MIRROR Number 0 - diameter 14mm	31602	802327900L1602020000000PZ	5
LARYNGEAL MIRROR Number 1 - diameter 16mm	31603	802327900L1602020000000PZ	5
LARYNGEAL MIRROR Number 2 - diameter 18mm	31604	802327900L1602020000000PZ	5
LARYNGEAL MIRROR Number 3 - diameter 20mm	31605	802327900L1602020000000PZ	5
LARYNGEAL MIRROR Number 4 - diameter 22mm	31606	802327900L1602020000000PZ	5
LARYNGEAL MIRROR Number 5 - diameter 24mm	31607	802327900L1602020000000PZ	5
LARYNGEAL MIRROR Number 6 - diameter 26mm	31608	802327900L1602020000000PZ	5
ADJUSTABLE MIRROR HANDLE	31615	80232790000Q03993100000W2	5
ADJUSTABLE MIRROR HANDLE	31616	80232790000Q03993100000W2	5
LARYNGOSCOPE SET 2 MILLER BL.0-1 - paediatric	34301	8023279Z120210030000000MQ	13
LARYNGOSCOPE SET 3 MC INT. BL.2-3-4 - adult	34302	8023279Z120210030000000MQ	13
LARYNGOSCOPE SET 4 MC INT. BL. 1-2-3-4 - adult	34303	8023279Z120210030000000MQ	13
LARYNGOSCOPE SET 3 BL. MILLER 0-1,MC INT. 0 - paediatric	34305	8023279Z120210030000000MQ	13
LARYNGOSCOPE DOCTOR SET 3 MILLER BL. 1-2-3	34306	8023279Z120210030000000MQ	13
LARYNGOSCOPE SET 3 BL. MILLER 00-0-1 - paediatric	34307	8023279Z120210030000000MQ	13
MILLER BLADE N.00 "OXY" - premature	34310	8023279Z12021003B300000XY	5
MILLER BLADE N.0 - premature/newborn	34311	8023279Z12021003B300000XY	5
MILLER BLADE N.1 - babies	34312	8023279Z12021003B300000XY	5
MILLER BLADE N.2 - adult	34313	80232790000V088097000007Z	5
MILLER BLADE N.3 - adults/large	34314	8023279Z12021003B300000XY	5
MC-INTOSH BLADE N.0 - newborn	34317	8023279Z12021003B300000XY	5
MC-INTOSH BLADE N.1 - babies	34318	8023279Z12021003B300000XY	5
MC-INTOSH BLADE N.2 - infants	34319	8023279Z12021003B300000XY	5
MC-INTOSH BLADE N.3 - adults	34320	8023279Z12021003B300000XY	5
MC-INTOSH BLADE N.4 - adults/large	34321	8023279Z12021003B300000XY	5
MC-INTOSH BLADE N.5 - adults/extra large	34322	8023279Z12021003B300000XY	5
GIMA GREEN F.O.LED ADULT SET 3 BLADES MC-INTOSH 2-3-4 - 2.5 V-22.000 lux	34327	8023279Z120210030000000MQ	13
GIMA GREEN F.O.LED ADULT SET 4 BLADES MC-INTOSH 1-2-3-4 - 2.5 V-22.000 lux	34328	8023279Z120210030000000MQ	13

GIMA GREEN F.O.LED ADULT SET 3 BLADES MC-INTOSH 2-3-4 - 3.5 V-27.000 lux	34329	8023279Z1202100300000000MQ	13
GIMA GREEN F.O.LED ADULT SET 4 BLADES MC-INTOSH 1-2-3-4 - 3.5 V-27.000 lux	34330	8023279Z1202100300000000MQ	13
MAXLITE F.O. PEDIATRIC SET 3 BLADES MILLER 00-0-1 - 2.5 V	34332	8023279Z1202100300000000MQ	13
MAXLITE F.O. ADULT SET 3 BLADES MC-INTOSH 1-2-3 - 2.5 V	34333	8023279Z1202100300000000MQ	13
MAXLITE F.O. ADULT SET 4 BLADES MC-INTOSH 1-2-3-4 - 2.5 V	34334	8023279Z1202100300000000MQ	13
MAXLITE F.O.LED ADULT SET 3 BLADES MC-INTOSH 2-3-4 - 2.5 V - 35.000 lux	34335	8023279Z1202100300000000MQ	13
MAXLITE F.O.LED PEDIATRIC SET 3 BLADES MILLER 00-0-1 - 2.5 V - 25.000 lux	34336	8023279Z1202100300000000MQ	13
MAXLITE F.O.LED ADULT SET 4 BLADES MC-INTOSH 1-2-3-4 - 2.5 V - 35.000 lux	34337	8023279Z1202100300000000MQ	13
MAXLITE F.O.LED ADULT SET 4 BLADES MC-INTOSH 1-2-3-4 - 3.5 V - 30.000 lux	34338	8023279Z1202100300000000MQ	13
PAEDIATRIC HANDLE - rough finish	34352	8023279Z1202100331000000PQ	13
STANDARD HANDLE - rough finish	34354	8023279Z1202100331000000PQ	13
"GIMA GREEN" PAEDIATRIC SET 2 BLADES MILLER 0-1	34451	8023279Z1202100300000000MQ	13
"GIMA GREEN" ADULT SET 3 BLADES MC-INTOSH 2-3-4	34452	8023279Z1202100300000000MQ	13
"GIMA GREEN" ADULT SET 4 BLADES MC-INTOSH 1-2-3-4	34453	8023279Z1202100300000000MQ	13
"GIMA GREEN" PAEDIATRIC SET 3 BLADES MILLER 0-1, MC-INT.0	34454	8023279Z1202100300000000MQ	13
"GIMA GREEN" DOCTOR SET 3 BLADES MILLER 1,2,3	34455	8023279Z1202100300000000MQ	13
"GIMA GREEN" RE-CHARGEABLE HANDLE 3.5V - pediatric	34456	8023279Z1202109931000902P	13
"GIMA GREEN" RE-CHARGEABLE HANDLE 3.5V - adult	34457	8023279Z1202109931CC090CT	13
"GIMA GREEN" F.O. BLADE MILLER N. 00 OXY - premature	34460	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MILLER N. 0 - newborn	34461	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MILLER N. 1 - infant	34462	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MILLER N. 2 - child	34463	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MILLER N. 3 - adult	34464	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MC-INTOSH N. 0 - newborn	34469	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MC-INTOSH N. 1 - infant	34470	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MC-INTOSH N. 2 - child	34471	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MC-INTOSH N. 3 - adult	34472	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MC-INTOSH N. 4 - adult large	34473	8023279Z12021003B3000000XY	5
"GIMA GREEN" F.O. BLADE MC-INTOSH N. 5 - adult X-large	34474	8023279Z12021003B3000000XY	5
"GIMA GREEN" PAEDIATRIC LED RECHARGEABLE BATTERY HANDLE 2.5V	34476	8023279Z1202100331000000PQ	13

"GIMA GREEN" ADULT LED RECHARGEABLE BATTERY HANDLE 2.5V	34477	8023279Z120210033100000PQ	13
"GIMA GREEN" PAEDIATRIC HANDLE 2.5V	34480	8023279Z1202109931BB090C9	13
"GIMA GREEN" ADULT HANDLE 2.5V	34481	8023279Z1202109931CC090CT	13
"GIMA GREEN" ADULT RE-CHARGEABLE LED HANDLE 3.5V	34482	8023279Z120210993100000ZR	13
"MAXLITE" FLEXI F.O. SET LED 2 BLADES MC-INTOSH 3, 4	34498	8023279Z120210030000000MQ	13
"GIMA MAXLITE" F.O. BLADE MILLER N. 0 - newborn	58051	8023279Z12021003B300000XY	5
"GIMA MAXLITE" F.O. BLADE MILLER N. 1 - infant	58052	8023279Z12021003B300000XY	5
"GIMA MAXLITE" F.O. BLADE MC-INTOSH N. 0 - newborn	58056	8023279Z12021003B300000XY	5
"GIMA MAXLITE" F.O. BLADE MC-INTOSH N. 1 - infant	58057	8023279Z12021003B300000XY	5
"GIMA MAXLITE" F.O. BLADE MC-INTOSH N. 2 - child	58058	8023279Z12021003B300000XY	5
"GIMA MAXLITE" F.O. BLADE MC-INTOSH N. 3 - adult	58059	8023279Z12021003B300000XY	5
"GIMA MAXLITE" F.O. BLADE MC-INTOSH N. 4 - adult large	58060	8023279Z12021003B300000XY	5
"GIMA MAXLITE" F.O. BLADE MC-INTOSH N. 5 - adult X-large	58061	8023279Z12021003B300000XY	5
MAXLITE FLEXI F.O. SET 1 BLADE MC-INTOSH 3	58070	8023279Z120210030000000MQ	13
MAXLITE FLEXI F.O. SET 2 BLADES MC-INTOSH 3, 4	58072	8023279Z120210030000000MQ	13
MAXLITE FLEXI F.O. LED SET 1 BLADE MC-INTOSH 3	58073	8023279Z120210030000000MQ	13
MAXLITE FLEXI F.O. BLADE N 2 MC-INTOSH	58078	8023279Z12021003B300000XY	5
MAXLITE FLEXI F.O. BLADE N 3 MC-INTOSH	58079	8023279Z12021003B300000XY	5
MAXLITE FLEXI F.O. BLADE N 4 MC-INTOSH	58080	8023279Z12021003B300000XY	5

intended purpose: Laryngoscopes are intended to visualize the larynx and allow the introduction of the endotracheal tube. The laryngeal mirrors are intended to examine the laryngeal cavities of patients allowing the user an overall hypopharyngolaryngeal view

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;
- (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, 09/10/2025

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

