



*Ministero della Salute*  
 DIPARTIMENTO DELL'INNOVAZIONE - DIREZIONE GENERALE DEL FARMACO E DEI  
 DISPOSITIVI MEDICI - Ufficio III

DSPDM/W/P-16385

**HAVING REGARD** to the 93/42/EEC Directive concerning medical devices;  
**HAVING REGARD** to the Legislative Decree (D.L.vo) no. 46/97 (and its following amendments) reporting the accomplishment of directive 93/42/EEC;  
**HAVING REGARD** to the petition of March 10 2005 lodged by the Company **GIMA S.p.A**, with set in 20122 Milano , Italy, via Paolo da Canobbio 37, VAT NUMBER 00734640154;  
**WHEREAS** that the petition company made the payments required by Ministerial Decree (D.M.) May 24,2004;  
**HAVING REGARD** to the official deeds;

**IT IS ATTESTED**

That the Company **GIMA S.p.A** b, with Manufacturing Plant Location in 20060 Gessate (MI), taly, via Monza 10 2 , VAT NUMBER 00734640154, has marked, as manufacturer, according to the Directive 93/42/EEC,the products:

Tongue depressors
Tongue depressors single use
Sphygmomanometer's accessories ( bracciali pere polmoni )
ORL examination accessories (loop, spoon, scoop, ear specula, laryngeal mirror)
Gynaecology single use products ( Gimabrsh, Papette Wallach Ayre Spatula,cotton swabs
Stretchers
Examination couches
Wheelchairs
Trolley
Stainless steel holloware
Mouthpieces
Steel tubes for aspirator
Colposcope
Dermatoscope
Tuning forks
Sterilizer drum
EGG electrodes (clamps and chests)
ECG ECO Gel
Lubricant Gel Lubrigima
Headlights
Tourniquets
Torches - Pen lights
Neurological hammers
Nystagmus spectacles

Resuscitator balloons			
Pill boxes, pulverizer, vials cutter			
Nasal forcep			
Pouches and rolls for sterilization			
Ear syringes			
Loupes (Keplerian, Galileian, Head Loupe)			
Perfection brushes			
ENT head mirrors, headlights			
Vaginal speculums			
Splints			
Surgical instruments			
Silicone tubes for medical use			
Vacuum suction cups			
Negativoscopes	<b>CODES</b>	27364	27365 27366
		27367	27368 27369
		27370	27372 27373
		27360	27361 27374
		27375	
Optometric charts		27380	27381 27382
		27383	27390 27391
		27392	27393
Air mattress: MASTER, RINT PLUS		28492	28493 28495
MASTER, RINT PLUS compressors		28482	28483 28498
Water mattress		28499	
Scialytic Lights		30700	30703 30713
		30717	30718 30721
		30723	30724 30701
		30711	
Saturno operating lights		30705	30706 30707
Solesud, halogen examination lights		30745	30746
Simplex halogen examination lights		30760	30761
Solenord halogen examination lights		30740	30741
Gimanord lights for dermatology		30750	30751
Wood blue lights		31189	31191 31192
		31195	31196
Otosopes - parker line		31435	31436 31437
		31440	31442
GIMALUX otoscopes		31520	31521 31522
Parker halogen otoscopes		31475	
Parker diagnostic sets		31444	31445
Gowlands otoscopes		31301	31302 31304
Gowlands ophthalmoscopes		31320	31326
Mayfield halogen ophthalmoscope		31340	
Heine halogen otoscopes-		31720	31725
Heine k180 Oto- ophthalmoscope K180 - set		31740	
Heine Omega ophthalmoscope		31750	
Heine mini 2000 halogen otoscopes		31700	31701 31702
		31705	
Littmann stethoscopes		32400	32405 32410
		32415	32416 32417

	32418	32419	32425
	32430	32435	32440
	32445		
Jotrap stethoscopes	32590	32581	32582
	32583	32584	
Wan stethoscopes	32570	32571	32572
	32575	32576	32577
	32509	32511	
Trad stethoscopes	32560	32561	32562
	32565	32566	32567
Classic stethoscopes	32537	32512	32516
Yton stethoscopes	32514	32530	
Duca stethoscopes	32520	32523	
Paediatric stethoscopes Wan Tai	32509	32511	32513
Regalite stethoscopes	32526		
Cardiology stethoscope Classic, Spirit Ter	32552	32553	
Tytan electronic stethoscope	32556		
ES-120 electronic stethoscope	32540		
Obstetric Stethoscopes	32501	32502	32505
Miller laryngoscopes: set, blades	34301	34310	34311
	34312	34313	34314
Mc-intosh laryngoscopes: set, blades	34302	34303	34318
	34319	34320	34321
F.o. miller laryngoscopes: set, blades	34330	34340	34341
	34342	34343	34344
F.o. mc-intosh laryngoscopes: set, blades	34334	34332	34346
	34347	34348	34349
Doctor set laryngoscopes	34304	34333	
Handles	34352	34354	34356
"Gima green" line laryngoscopes	34460	34461	34462
	34463	34464	34470
	34471	34472	34473
	34451	34452	34453
	34364	34481	34480
Set Flexi F.o.	34492		
GIMA Blades F.O. disposable	34481	34364	34359
	34365	34366	34375
	34376	34377	34381
Light source Gima 150 W	30801		
Double light source	30802		
LUT XENON light source - 180 W	30804		
LUT halogen light source - 250 W	30805		
XENON light source 300W	30809		
Flyer Handle	30795		
Gynolight	29962		
Otosclilo Irrigation device	25815		
Amnioscope set complete	29970		
Ac/Dc Trasformer Gima 5	31130		
Manual and electrical hoists	27730	27755	

The products, according to the art. 4 of the mentioned Directive, can freely circulate and can be commercialised in Italy and in all the territory of the European Union.

This certificate is issued on the interested party's request according to the law and for export.

THE OFFICE MANAGER  
Dr Giuseppe Ruocco



27 MAR 2005