



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

*DSFDM/III/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  |

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|   |              |                   |  |
|---|--------------|-------------------|--|
| 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 |       |       |
| Jotarap stethoscopes                       | 32580 | 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 |       |       |
| Otosillo Irrigation device                 | 25815 |       |       |
| Amnioscope set complete                    | 29970 |       |       |
| Ac/Dc trasformer Gima 5                    | 31130 |       |       |
| Manual and electrical hoists               | 27750 | 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