APPROVAZIONE DEL SISTEMA COMPLETO DI GARANZIA DI QUALITA'

FULL QUALITY ASSURANCE SYSTEM APPROVAL

Secondo l'allegato II della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24.02.97)
According to Annex II of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

CERTIFICATO CE n. 2194
EC CERTIFICATE No

ICIM S.p.A.

Organismo Notificato n. 0425
Notified Body No. 0425

visto l'esito delle verifiche condotte in conformità all'allegato II, punto 3 della Direttiva Europea 93/42/CEE
on the basis of the assessment performed according to Annex II, point 3 of EC Directive 93/42/CEE

dichiara che il sistema completo di garanzia di qualità attuato da:
declares that the full quality assurance system enforced by:

FAST ASSEMBLER S.r.l.

Sede legale: Piazzale Cadorna, 13 - 20123 Milano
Unità Operativa: Via San Domenico, 11/13 - 20010 Bareggio MI

per i seguenti tipi di prodotti - processi - servizi:
for the following kinds of products - processes - services:

Sterilizzatrici ad aria calda.
Sterilizzatrici a palline di quarzo.

è conforme ai requisiti dell'allegato II della Direttiva Europea 93/42/CEE.
is in compliance with the requirements set out in Annex II of EC Directive 93/42/CEE.

Per identificazione dei modelli di prodotto vedere l'allegato 1.
For identification of the model type see Annex 1.
L'allegato 1 è da considerarsi parte di questo Certificato.
Annex 1 is integral part of this Certificate.

Data prima emissione 01/06/2010
Date of first issue

Emissione corrente 01/06/2010
Current issue

Data di scadenza 31/05/2015
Expiring Date

Dott. Ing. Tullio Badino

Ministero della Salute

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

DdF DM/ III / 1° - 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 loged 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 – 10. aggiunta data
EGG electrodes (clamps and chests)
ECG ECO Gel
Lubricant Gel Lubrigima
Headlights
Tourniquets
Torches – Pen lights
Neurological hammers
Nystagmus spectacles

Resuscitator bailoons				
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	**CODES**	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	
Otoscopes – 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 ototoscopes-		31720	31725	
Heine k180 Oto- ophthalmoscope K180 – set		31740		
Heine Omega ophthalmoscope		31750		
Heine mini 2000 halogen otoscopes		31700	31701	31702
		31705		
Liitmann siethoscopes		32400	32405	32410
		32415	32416	32417

	32418	32419	32435
	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	32507	32512	32516
Yton stethoscopes	32514	32530	
Duca steithoscopes	32520	32523	
Paediatric stethoscopes Wan Tai	32509	32511	32513
Regalite stethoscopes	32526		
Cardiology stethoscope Classic, Spirit Ter	32552	32552	
Tytan electronic stethoscope	32556		
ES-120 electronic steithoscope	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	34335	34345
	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	34370
	34375	34377	34381
Light source Gima 150 W	30801		
Double light source	30802		
LUT XENON light source 180 W	30804		
LUT Iodogen light source 250 W	30805		
XENON light source 300W	30807		
Flyer Handle	30795		
Gynolight	29962		
Otoscillo Irrigation device	25815		
Amnioscope set complete	27770		
AC/Dc trasformer Gima 5	31130		
Manual and electrical hoists	27740	27745	

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 in issued on the interested party's request according to the law and for export.

THE OFFICE MANAGER
Dr Giuseppe Rubecco

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) – Italy
www.gimaitaly.com

EXPORT DIVISION
tel. +39 02 953854209/221/225
fax +39 02 95380056
export@gimaitaly.com

Gessate, 7 February 2012

CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC

as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

GIMA INTERNATIONAL CATALOGUE

meet the provisions of the following Council Directive (when applicable)

93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

as below:

A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).

B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

GIMA S.p.A.
Q.A. Department
Nicola Manzoni

CERTIFICATO DEL SISTEMA DI GESTIONE PER LA QUALITÀ

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Si dichiara che il sistema di gestione per la Qualità dell'Organizzazione:
We certify that the Quality Management System of the Organization:

Reg. No: 10164 – M

GIMA S.p.A.

Indirizzo/*Address:*

Via Marconi, 1
20060 Gessate MI Italia

È conforme alla norma/*Is in compliance with the standard:*

UNI CEI EN ISO 13485:2012
ISO 13485:2003

Per i seguenti prodotti-servizi/*For the following products-services*

Commercializzazione, confezionamento ed assistenza di: dispositivi medici (DM), diagnostici in vitro (IVD),accessori e supporti ad uso medico

Trade, packeging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories and aids

EA: 29 a

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti essenziali CERMET.
Maintenance of the certification is subject to annual survey and dependent upon the observance of CERMET basic requirements
Riferirsi al manuale qualità per i dettagli delle esclusioni ai requisiti della norma UNI CEI EN ISO 13485:2012
Refer to quality manual for details of exclusion of ISO 13485:2003 requirements
La presente certificazione è stata rilasciata in conformità al Regolamento Tecnico Accredia / Sincert RT 20
This certification has been granted in compliance with the Accredia / Sincert Technical Regulation TR 20

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute dello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 051.459.3.111 o e-mail: infobologna@cermet.it/ *In case of punctual and updated information about any changes to the certification status, please contact phone number +39 051.459.3.111 o e-mail: infobologna@cermet.it*

Rilascio certificato/*Certificate issuance:*	2012-10-15
Ultima modifica/*Last modification:*	2012-10-15
Prossimo rinnovo/*Following renewal:*	2015-10-14

Direttore Commerciale e Operativo
Sales and Operations Manager
Gianpiero Belcredi

Direttore Generale
General Manager
Rodolfo Trippodo

IAF ACCREDIA CERMET

CE Marking

CE Marking is a legal requirement for medical devices intended for sale in Europe.
There are three European CE marking Directives that specifically apply to medical devices manufacturers:

1. The Medical Devices Directive (MDD) applies to all general medical devices not covered by the Active Implantable Medical Devices Directive or the In Vitro Diagnostics Directive.
2. The Active Implantable Medical Devices Directive (AIMDD) applies to all active devices and related accessories intended to be permanently implanted in humans.
3. The In Vitro Diagnostics Directive (IVDD) applies to all devices and kits used away from the patient to make a diagnosis of patient medical conditions (IVD are the analysis of medical samples, such as blood, tissues, or urine, that are taken from patients or healthy individuals).

Most of medical equipments are under MDD, directive 93/42/EEC, updated by 2007/47/EEC and are classified as below:

Class I ➢ producers/suppliers must prepare technical documentation and after having obtained full quality system registration, are entitled to self-declare (Declaration of Conformity) their compliance with CE. The elements that should be included in the Declaration of Conformity are:

- *Name of the device, including model number and trade name.*
- *Manufacturer/Supplier name and address.*
- *Name of company quality management representative.*
- *Conformity assessment route to compliance.*
- *Standards that have been applied.*
- *Name and signature of a senior management representative and date signed.*

Class IIa/b ➢ producers must implement a QUALITY MANAGEMENT SYSTEM (QMS) most commonly achieved using ISO 13485* standard; prepare a technical file with detailed information demonstrating compliance with health and safety requirements of directive 93/42/EEC, 2007/47/EEC and submit all to a Notified Body. After this, the Notified Body will issue a CE CERTIFICATE reporting the Notified Body identifying number.

Class III ➢ No items sold by Gima

In Vitro Diagnostics Directive (IVDD) are under directive 98/79/EC and require a Notified Body CE Certificate

93/42/EEC, 2007/47/EEC and 98/79/EC CE CONFORMITY:

CLASS I 93/42/EEC	CLASS II 93/42/EEC	CLASS III 93/42/EEC	IN VITRO	98/79/EC
Most of Gima products	Some Gima products	No products sold by Gima	Self test	Professional test
Self declaration	Notified Body CE Certificate	Notified Body CE Certificate	Notified Body CE Certificate	Self declaration

***ISO 13485** is an ISO standard, published in 2003, that represents the requirements for a comprehensive management system for the design and manufacture of medical devices.