

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

A handwritten signature in black ink, appearing to read 'N. Manzoni', with a stylized flourish at the end.



Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

## Quality Management System Certificate ISO 9001:2015

We certify that the Quality Management System of the Organization:

### **GIMA S.p.A.**

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer  
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.  
Società con socio unico,  
soggetta all'attività di  
direzione e coordinamento di  
Kiwa Italia Holding Srl  
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40057 Granarolo dell'Emilia  
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www.kiwacermet.it

### **GIMA S.p.A.**

#### **Registered Headquarters**

- Via Grossi, 2 20121 Milano Italia

#### **Certified Sites**

- Via Marconi, 1 20060 Gessate ( MI ) Italia



Reg. Number	10164 - M	Valid From	2018-10-01
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Valid until	2021-10-14		

## Quality Management System Certificate **ISO 13485:2016**

We certify that the Quality Management System of the Organization:

### **GIMA S.p.A.**

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

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

Chief Operating Officer  
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

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SGQ N° 007A  
SGA N° 010D  
PRD N° 069B  
FSM N° 0041  
PRS N° 089C



# GIMA

## CLINIC PLUS SUCTION 2x4 l jar 230V with footswitch, flow regulator

<b>Code:</b>	<b>28198</b>
<b>Category:</b>	<b>Hospital suction pumps aspirators</b>
<b>Unit of sale:</b>	<b>1 pc.</b>
<b>Minimum order:</b>	<b>1</b>
<b>Type:</b>	<b>Medical device</b>
<b>Class:</b>	<b>II A</b>
<b>NSIS:</b>	<b>590729</b>
<b>CND:</b>	<b>Z120105</b>
<b>EAN13:</b>	<b>8023279281989</b>



**Description:** **CLINIC PLUS aspirator - 2 x 4 l - 220-230 V - with footswitch and flow diverter**

New innovative range of high vacuum, high flow aspirator ideal for hospitals.  
Pump piston type, lubrication and maintenance free. Supplied with hydrophobic 99% bacterial filter, vacuum gauge for control of vacuum and 2 autoclavable jars made in makrolon with ml graduation and double security valve.

Available on request 2 or 3 litre disposable liners.

Range includes version with foot switch and flow direction regulator, 110 and 230 V.

Four antistatic castors, two of which with brake, allow a perfect mobility.

User manual in GB, FR, IT, ES, DE.  
Made in Italy.

**Technical Specifications:**

- Operating voltage: 230 V / 50-60 Hz (110 V on request)
- Maximum suction: 0.90 bar (675 mmHg)
- Flow: 60 l/min
- Operating cycle: continuous
- Power: 230 VA
- Norms: CEI 62-5 (IEC 601-1) 93/42 EEC
- Made in Italy

**Standard accessories:**

- Foot switch
- Flow direction diverter, that allows to direct suctioned liquids to any of the 2 jars