



Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2020-05-06
Valid until	2021-10-14		

Previous expiry date

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:

Management of design and manufacturing, trade, packaging and assistance of: medical devices (DM), in vitro-diagnostic medical devices (IVD), accessories

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.

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

Via Cadriano, 23  
40057 Granarolo dell'Emilia  
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: [info@kiwacermet.it](mailto:info@kiwacermet.it)

[www.kiwa.it](http://www.kiwa.it)

**CERMET**

**GIMA S.p.A.**

**Registered Headquarters**

- Via Grossi, 2 20121 Milano Italia

**Certified Sites**

- Via Marconi, 1 20060 Gessate ( MI ) Italia





# GIMA

PROFESSIONAL MEDICAL PRODUCTS

Gima S.p.A.

Via Marconi, 1 - 20060 Gessate (MI) Italy

[gima@gimaitaly.com](mailto:gima@gimaitaly.com) - [export@gimaitaly.com](mailto:export@gimaitaly.com)

[www.gimaitaly.com](http://www.gimaitaly.com)

---

## **TERMOMETRO ECOLOGICO ECO-THERMOMETER**

**Manuale d'uso - User manual**

---



**ATTENZIONE:** Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

**ATTENTION:** The operators must carefully read and completely understand the present manual before using the product.

Mercury free clinical thermometer is a kind of measuring device for patient's temperature, and it can be used to measure the temperature of patient's mouth or armpit or anus.

The product is in compliance with EN12470-1:2000+A1:2009, Clinical thermometers - Part 1: Metallic liquid-in glass thermometers with maximum device.

1. The conditions of use: measuring temperature range should be between 35°C to 42°C, and the environment temperature should be 20°C to 30°C; if the temperature for storage is less than 20°C, please put the thermometers in the temperature 20°C to 30°C for at least 1-2 hours or 30°C to 35°C for ten minutes before use or test.
2. The temperature must be less than 42°C when it is stored and transported.
3. Storage of the thermometer: after use, swing the metallic liquid down.  
Then clean it and put it in plastic case to avoid any damage.

**Please make the liquid of thermometers down according to following steps:**

1. Put a thermometer into a shaker, and screw its cap tightly.
2. Hold two wings of the shaker by your thumb and forefinger.
3. Shake the shaker (see picture on the right).










#### Operation procedures

1. The liquid column shall fall below the lowest numbered scale mark before use, then clean and sterilize the clinical thermometer in medical alcohol.
2. Be careful to put it below the tongue of patients for oral clinical thermometer and tell them to close their mouth tightly.
3. A clinical thermometer for rectal use is applied some lubricator before inserting it in the anus.
4. Be careful to put it below the armpit of patients if measuring armpit position and tell them to tight it tightly.  
Please read the number of the clinical thermometer about 5 minutes after above measuring steps.

#### Warning

1. It is not suitable to use oral clinical thermometers for not more than ten years' children.
2. Warn patients against chewing, speaking and playing when the clinical thermometers are below the tongue of patients.
3. Need to let sick children lie quietly and help them to hold another end of the clinical thermometers for rectal use in case it is inserted too deep, or it slips from the anus.
4. Avoid having a bath, eating or smoking half an hour before taking body temperature.
5. It is not designed for special applications (e.g. thermometers for premature babies, ovulation thermometers).
6. Inspect the clinical thermometer once a year.
- e. Disposal of the Clinical thermometers.

The metallic liquid is an alloy consisting of gallium, indium and tin. this clinical thermometer should be handled with care. In particular, care should be taken to avoid dropping the instrument or treating it in any way that could result in damage. When the clinical thermometers are broken, cleaning split metallic liquid by a damp cloth with soap suds.

<b>REF</b>	IT - Codice prodotto GB - Product code		IT - Conservare al riparo dalla luce solare GB - Keep away from sunlight	<b>CE</b>	IT - Dispositivo medico conforme alla Direttiva 93/42/CEE GB - Medical Device complies with Directive 93/42/EEC
<b>LOT</b>	IT - Numero di lotto GB - Lot number		IT - Conservare in luogo fresco ed asciutto GB - Keep in a cool, dry place		IT - Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso GB - Caution: read instructions (warnings) carefully
	IT - Fabbricante GB - Manufacturer		IT - Leggere le istruzioni per l'uso GB - Consult instructions for use	<b>EC REF</b>	IT - Rappresentante autorizzato nella Comunità europea GB - Authorized representative in the European community
	IT - Data di fabbricazione GB - Date of manufacture		IT - Non contiene mercurio GB - Mercury free		



**25586 / 25589**  
**CR.W00**



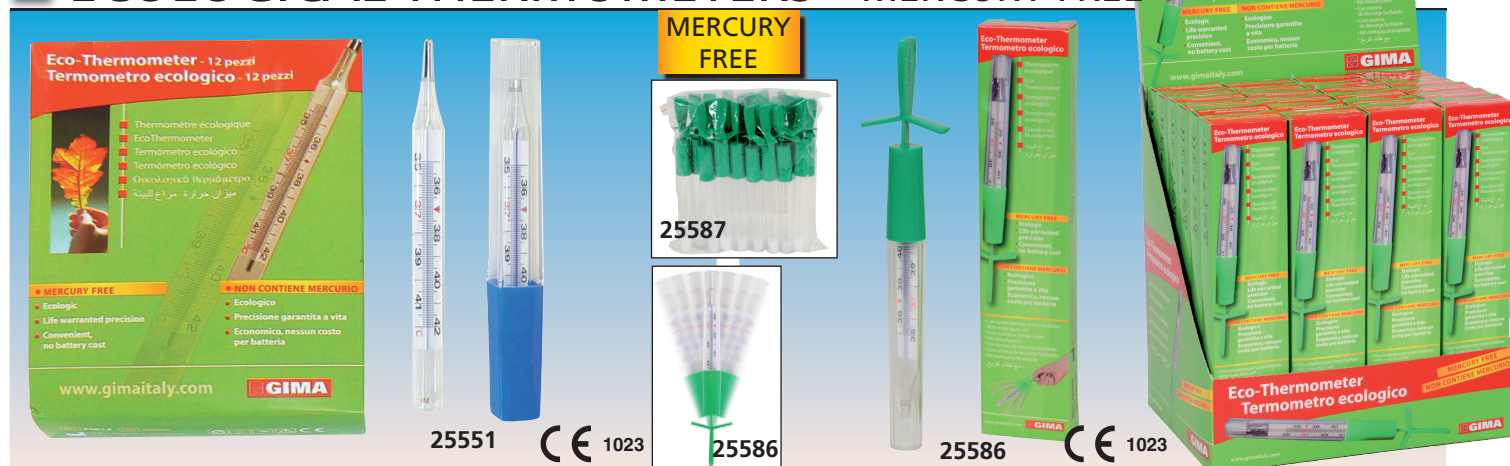
Wuxi Medical Instrument Factory Co., Ltd.  
No. 43 Xixin Road, ZhangJing, Xibei Town,  
Wuxi city, Jiangsu, 214194, China  
Made in China



Lotus NL B. V.  
Koningin Julianaplein 10, 1e Verd, 2595AA  
The Hauge, Netherlands



## ECOLOGICAL THERMOMETERS - MERCURY FREE



- 25551 ECOLOGICAL OVAL THERMOMETER - box of 12
  - 25587 SHAKER for ecological thermometers - box of 24
- Mercury free clinical thermometer with gallium alloy instead of mercury. Safe, precise and functional. Glass structure.

- 25586 ECOLOGICAL OVAL THERMOMETER with shaker - box
  - 25589 ECOLOGICAL OVAL THERMOMETER with shaker display box of 24 pcs.
- Same as 25551 but supplied with a shaker to help shake down gallium after use.

## POCKET EAR THERMOMETER

- 25579 POCKET EAR THERMOMETER

Small, easy to clean, cover free design ear thermometer. Home use.

### TECHNICAL SPECIFICATIONS

Measurement Range:	34-44 °C (93.2-111.2 °F) $\pm 0.2$ °C ( $\pm 0.4$ °F)
Response time:	1-2 seconds
Battery:	Lithium 3 V (CR2032) - life approx 4,000 measurements
Size - weight:	114x35x40 mm - 35 g (including batteries)

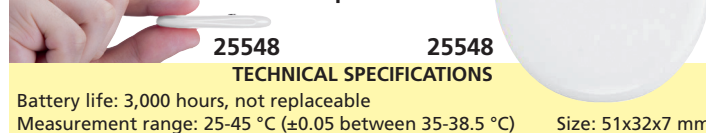


## WIRELESS THERMOMETER

- 25548 TEMP SITTER - baby wireless thermometer

Accurate and innovative thin thermometer. Transmission to mother smartphone APP (iOS and Android). To be placed under baby armpit. High temp alarm can be set in the APP. Waterproof and material of safe quality. Supplied with 10 adhesives to fix thermometer to baby armpit.

- 25547 ADHESIVE TO FIX TEMP SITTER - box of 10 - spare



### TECHNICAL SPECIFICATIONS

Battery life: 3,000 hours, not replaceable	Size: 51x32x7 mm
Measurement range: 25-45 °C ( $\pm 0.05$ between 35-38.5 °C)	

## BABY THERMOMETERS

60 SECONDS CE 0197



- 25555 PANDA DIGITAL THERMOMETER °C - hang box water-proof, fever alarm

30 SECONDS CE 0476

- 25566 FROG DIGITAL THERMOMETER °C - hang box - flexible tip

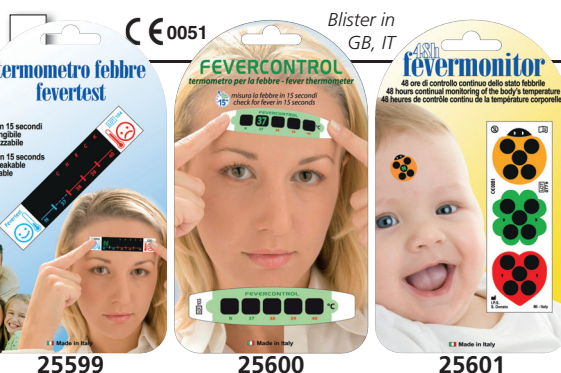
## NIPPLE-LIKE DIGITAL THERMOMETER

- 25569 NIPPLE-LIKE DIGITAL PACIFIER THERMOMETER °C
- Individually packed in cardboard box, memorizes last temperature. Auto power-off. Display range 32.0°C - 42.0°C, with accuracy  $\pm 0.1$ °C.

1.5 V button battery included.



25569



## LIQUID CRYSTAL THERMOMETERS

Non toxic, mercury free, safe, unbreakable, reliable, long lasting, easy to read, liquid crystal thermometers. 10 languages manual. Made in Italy.

### REUSABLE FOREHEAD THERMOMETERS

- 25599 FEVERTEST - bag of 10 blister
- It indicates the normal temperature or fever in 15 seconds.
- 25596 FEVERTEST BULK - box of 100 - hospital use
- 25600 FEVERCONTROL - bag of 10 blister
- It indicates temperature in 15 seconds with graduation of 0.5 °C. Safe, fast, accurate, non toxic, unbreakable.

### BODY TEMPERATURE MONITOR

- 25601 48h FEVER MONITOR - bag of 10 blister of 3 pcs.
- Innovative "continual" fever indicator for 48h monitoring.



25596



## REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

DM000213603	TERMOMETRU DIGITAL	Medline	RIGID, MC-102		China	WUXI EXANOVO MEDICAL INSTRUMENT CO., LTD.	Î.C.S. FARMINA S.R.L.	Rg04-000138	18-06-2019	
DM000213604	TERMOMETRU DIGITAL	Medline	INSTANT, MC-103		China	WUXI EXANOVO MEDICAL INSTRUMENT CO., LTD.	Î.C.S. FARMINA S.R.L.	Rg04-000138	18-06-2019	
DM000213602	TERMOMETRU DIGITAL	Medline	RAPID, MC-101R		China	WUXI EXANOVO MEDICAL INSTRUMENT CO., LTD.	Î.C.S. FARMINA S.R.L.	Rg04-000138	18-06-2019	
DM000213601	TERMOMETRU DIGITAL CU VÂRF FLEXIBIL	Medline	RAPID, MC-403S		China	WUXI EXANOVO MEDICAL INSTRUMENT CO., LTD.	Î.C.S. FARMINA S.R.L.	Rg04-000138	18-06-2019	
DM000042109	TERMOMETRU FĂRĂ MERCUR		CR.W00		China	WUXI MEDICAL INSTRUMENT FACTORY CO., LTD	RAILSMED S.R.L.	A07.PS-01.Rg04-8	10-01-2018	
DM000243304	TERMOMETRU FĂRĂ MERCUR	EVOLU CLASSIC	CR.W00		China	WUXI MEDICAL INSTRUMENT FACTORY CO., LTD	REPREZENTANȚA DIN LETONIA FORANS S.R.L.	Rg04-000293	20-11-2019	
DM000213618	TERMOMETRU FĂRĂ MERCUR		CR.W00		China	WUXI MEDICAL INSTRUMENT FACTORY CO., LTD	Î.C.S. FARMINA S.R.L.	Rg04-000138	18-06-2019	
DM000209914	TERMOMETRU FĂRĂ MERCUR		CR.W00		China	WUXI MEDICAL INSTRUMENT FACTORY CO., LTD	Î.M. BECOR S.R.L.	Rg04-000129	07-06-2019	

☒ Содержит([Producatorul], 'wuxi') И Содержит([Denumire], 'termom').