

## APPROVAL

EC Directive 98/79/EC Annex IV, Article 3  
Full Quality Assurance System  
In vitro diagnostic medical devices

Registration No.: HL 60018284 0001

Report No.: 21127789 002

Manufacturer: GIMA SPA  
Via Monza 102  
20060 Gessate MI  
Italy

Scope: Design and Development, Manufacture and Sales of  
In-vitro diagnostic rapid test

Products: see attachment


Date of Expiry: 17.04.2012

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 11.06.2007



Notified Body

  
Dr. H. Lüdemann

**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

**TÜV Rheinland**  
**Product Safety GmbH**  
**Am Grauen Stein, D-51105 Köln**

**Attachment to**  
**Registration No.:** HL 60018284 0001  
**Report No.:** 21127789 004

**Manufacturer:** GIMA SPA  
Via Monza 102  
20060 Gessate MI  
Italy

**Scope:** Products:

Glucose self testing device  
- Test glicemia

Cholesterol self testing device  
- Test colesterolo  
- Realcheck test colesterolo  
- Test colesterolo New Promitaly  
- Test colesterolo Farmamed  
- Test colesterolo Menarini

Pregnancy self testing device  
- Realcheck test di gravidanza

PSA self testing device  
- Test prostata  
- Realcheck test prostata  
- Fatti il test prostata

Cologne, 09.09.2009



**Certification Body**

  
Dr. H. Lüdemann

**TÜV Rheinland**  
**Product Safety GmbH**  
**Am Grauen Stein, D-51105 Köln**

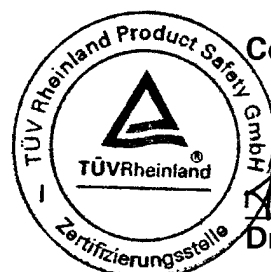
**Attachment to**  
**Registration No.:** HL 60018284 0001  
**Report No.:** 21127789 004

**Manufacturer:** GIMA SPA  
Via Monza 102  
20060 Gessate MI  
Italy

**Scope:** Products:

- Pregnancy test for self-testing
- Test gravidanza strip 4 mm, GIMA
  - Prompt strip
  - Test gravidanza midstream GIMA 1 pc
  - Test gravidanza midstream GIMA 2 pcs
  - Test gravidanza Dimostra 1 pc
  - Test gravidanza Dimostra 2 pcs
  - Prompt midstream 1 pcs
  - Prompt midstream 2 pcs
  - Rivela test gravidanza 1 pc
  - Rivela test gravidanza 2 pcs
  - Miapharmacia test gravidanza 2 pcs
  - Test gravidanza Farmamed 1 pc
  - Test rapido gravidanza Angelini 1 pc
  - Test rapido gravidanza Angelini 2 pcs
  - SI o NO test di gravidanza 1 pc
  - SI o NO test di gravidanza 2 pcs

Cologne, 09.09.2009



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**Scope:** Products:

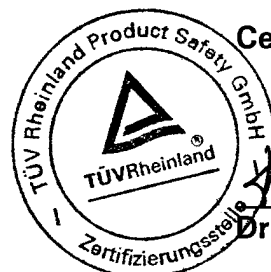
Ovulation test for self-testing

- Test di ovulazione midstream GIMA
- Test di ovulazione strip GIMA
- Miapharmacia test fertilita
- Prompt-ovu midstream
- Prompt-ovu strip
- Test rapido ovulazione Farmamed

Menopause test for self-testing

- GIMA Test Menopausa
- Realcheck Test Menopausa
- Miapharmacia Test Menopausa
- Prompt-meno Midstream
- Test rapido menopausa Farmamed

Cologne, 09.09.2009



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Via Monza 102  
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Italy

**Scope:** Products:

Fecal Occult Blood Self-Test

- Test colon-retto
- Realcheck test colon-retto
- Miapharmacia autodiagnosi malattie gastrointestinali

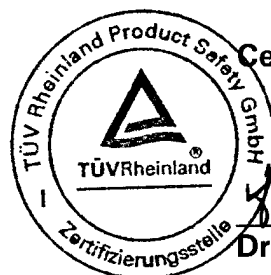
Helicobacter Pylori self-testing devices

- Test ulcera H-Pylori
- Fatti il test Helicobacter

Allergy specific self-testing devices

- test allergia gatto

Cologne, 09.09.2009



**Certification Body**

  
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**Dr. H. Lüdemann**