# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**IVDD Annex IV, Art.3**

Registration No.: HL 1182588-1

Manufacturer: GIMA SPA
Via Marconi 1
20060 Gessate MI
Italy

Products: In vitro diagnostic rapid tests for self-testing

Product groups included:

- Pregnancy tests (detection of hCG hormone)
- Tests for the detection of prostate specific antigen (PSA)
- Tests for the detection of Helicobacter pylori

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.