

APPROVAL

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

Registration No.: HL 60023971 0001

Report No.: 21138422 002

Manufacturer: DRG Instruments GmbH
Frauenbergstr. 18
35039 Marburg
Deutschland

Scope: Design/Development and Manufacture of in vitro
diagnostic reagents

Products: see attachment

Replaces Approval, Registration No.: HL 60015180 0001

Date of Expiry: 04.02.2014

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, 05.02.2009



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.



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



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HL 60023971 0001
Report No.: 21138422 004

Manufacturer: DRG Instruments GmbH
Frauenbergstr. 18
35039 Marburg
Deutschland

Scope:

Products:
Reagents and reagent products for evaluating
the risk of trisomy 21:
- Pregnancy associated Plasma Protein-A ELISA, EIA-2397
- Free β -HCG ELISA, EIA-4718

Reagents and reagent products for determining
the tumoral marker PSA:
- PSA ELISA, EIA-1551
- Free PSA ELISA, EIA-1550
- Free PSA ELISA, EIA-4189
- Total PSA ELISA, EIA-3719

Reagents and reagent products for diagnosing
phenylketonuria:
- Phenylalanine PKU, ENZ-4502 and ENZ-4743

Date 14.04.2011



Certification Body


Dr. H. Lüdemann