



TÜVRheinland®

## EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6

Full Quality Assurance System  
In Vitro Diagnostic Medical Devices

Registration No.: HL 60084590 0001

Report No.: 21195407 001

**Manufacturer:** DRG Instruments GmbH  
Frauenbergstr. 18  
35039 Marburg  
Deutschland

**Products:** Design/Development and Manufacture of in vitro  
diagnostic reagents

Products: see attachment

Replaces Approval, Registration No.: HL 60023971 0001

**Expiry Date:** 2018-04-02

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.

**Effective Date:** 2013-04-03

**Date:** 2013-04-03



Notified Body

  
Dr. H. Lüdemann

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HL 60084590 0001  
**Report No.:** 21195407 001

**Manufacturer:** DRG Instruments GmbH  
Frauenbergstr. 18  
35039 Marburg  
Deutschland

Products included:

Reagents and reagent products for evaluating  
the risk of trisomy 21:

- Pregnancy associated Plasma Protein-A ELISA, EIA-2397
- Free  $\beta$ -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:** 2013-04-03



**Notified Body**

  
**Dr. H. Lüdemann**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HL 60084590 0001  
**Report No.:** 21195407 001

**Manufacturer:** DRG Instruments GmbH  
Frauenbergstr. 18  
35039 Marburg  
Deutschland

Products included:  
Reagents and reagent products for determining  
infection diseases:

- Chlamydia trachomatis IgA, EIA-3461
- Chlamydia trachomatis IgG, EIA-3462
- Chlamydia trachomatis IgM, EIA-3463
- Toxoplasma gondii IgA, EIA-3683
- Toxoplasma gondii IgG, EIA-3519
- Toxoplasma gondii IgM, EIA-3520
- Rubella IgG, EIA-3510
- Rubella IgM, EIA-3511
- CMV IgG, EIA-3468
- CMV IgM, EIA-3469

**Date:** 2013-04-03



**Notified Body**

  
**Dr. H. Lüdemann**