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 maunfactured products according to section 6 is required.

Effective Date: 2013-04-03

Date: 2013-04-03

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

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Doc. 1/2, Rev. 0

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 ß-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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2013-04-03

Dr. H. Lüdemann

TÜVRheinland®

Doc. 2/2, Rev. 0

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2013-04-03

Dr. H. Lüdemann