

EC Certificate



Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1170693-1

Manufacturer: DRG Instruments GmbH
Frauenbergstr. 18
35039 Marburg
Germany

Products: In vitro diagnostic reagents

Products included:

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 Free ELISA, EIA-4189
- PSA Total ELISA, EIA-3719
- Free PSA, HYE-5371
- PSA (HYBRID-XL), HYE-5370

Reagents and reagent products for diagnosing phenylketonuria:

- Phenylalanine PKU, ENZ-4502 and ENZ-4743

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.

Report No.: 1106497-20

Effective date: 2022-04-27

Expiry date: 2025-05-26

Issue date: 2022-05-12



Dipl.-Ing. Sven Hoffmann
TÜVRheinland LGA Products GmbH
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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.

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Reagents and reagent products for determining infectious 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 IgG, EIA-5778
- CMV IgM, EIA-3469

Replaces Certificate, Registration No.: HL 60128323 0001

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