



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 60135571 0001

Report No.: 21209201 011

**Manufacturer:** Institut Virion\Serion GmbH  
Friedrich-Bergius-Ring 19  
97076 Würzburg  
Deutschland

**Products:** Immunserological in vitro diagnostic medical devices  
to be used in infectious disease diagnostics

(see attachment for products included)

Replaces Approval, Registration No.: HL 60093162 0001

**Expiry Date:** 2024-04-06

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:** 2019-04-07

**Date:** 2019-03-28

Notified Body

Dipl.-Ing. (FH) D. Wiedemuth



**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 60135571 0001  
**Report No.:** 21209201 011

**Manufacturer:** Institut Virion\Serion GmbH  
Friedrich-Bergius-Ring 19  
97076 Würzburg  
Deutschland

**Products included:**

- SERION ELISA classic CYTOMEGALOVIRUS IgG
- SERION ELISA classic CYTOMEGALOVIRUS IgM
- SERION ELISA classic CYTOMEGALOVIRUS Avidity reagent
- SERION ELISA classic TOXOPLASMA gondii IgG
- SERION ELISA classic TOXOPLASMA gondii IgM
- SERION ELISA classic TOXOPLASMA gondii Avidity reagent
- SERION ELISA classic CHLAMYDIA IgG
- SERION ELISA classic CHLAMYDIA IgA
- SERION ELISA classic CHLAMYDIA pneumoniae IgG
- SERION ELISA classic CHLAMYDIA pneumoniae IgA
- SERION ELISA classic CHLAMYDIA pneumoniae IgM
- SERION ELISA classic RUBELLA IgM
- SERION ELISA classic RUBELLA IgG
- SERION ELISA classic RUBELLA Avidity reagent
- SERION ELISA classic CHLAMYDIA trachomatis IgA
- SERION ELISA classic CHLAMYDIA trachomatis IgG
- SERION ELISA classic CHLAMYDIA trachomatis IgM

**Notified Body**



**Date:** 2019-03-28

*D. Wiedemuth*  
**Dipl.-Ing. (FH) D. Wiedemuth**

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

Doc. 2/4, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HL 60135571 0001  
**Report No.:** 21209201 011

**Manufacturer:** Institut Virion\Serion GmbH  
Friedrich-Bergius-Ring 19  
97076 Würzburg  
Deutschland

**Products included:**

- SERION ELISA control
- SERION ELISA control CHLAMYDIA IgG
- SERION ELISA control CHLAMYDIA IgA
- SERION ELISA control CHLAMYDIA pneumoniae IgG
- SERION ELISA control CHLAMYDIA pneumoniae IgA
- SERION ELISA control CHLAMYDIA pneumoniae IgM
- SERION ELISA control CHLAMYDIA trachomatis IgA
- SERION ELISA control CHLAMYDIA trachomatis IgG
- SERION ELISA control CHLAMYDIA trachomatis IgM
- SERION ELISA control CYTOMEGALOVIRUS IgG
- SERION ELISA control CYTOMEGALOVIRUS IgM
- SERION ELISA control CYTOMEGALOVIRUS Avidity reagent
- SERION ELISA control RUBELLA-VIRUS IgM
- SERION ELISA control RUBELLA-VIRUS IgG
- SERION ELISA control RUBELLA-VIRUS Avidity reagent
- SERION ELISA control TOXOPLASMA gondii IgG
- SERION ELISA control TOXOPLASMA gondii IgM
- SERION ELISA control TOXOPLASMA gondii avidity reagent

**Notified Body**



**Date: 2019-03-28**

*D. Wiedemuth*  
**Dipl.-Ing. (FH) D. Wiedemuth**

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

**Attachment to  
Certificate**

**Registration No.:** HL 60135571 0001  
**Report No.:** 21209201 011

**Manufacturer:** Institut Virion\Serion GmbH  
Friedrich-Bergius-Ring 19  
97076 Würzburg  
Deutschland

**Products included:**

- SERION immunoControl CYTOMEGALOVIRUS IgM
- SERION immunoCONTROL CHLAMYDIA pneumoniae IgM
- SERION immunoCONTROL CHLAMYDIA pneumoniae IgG
- SERION immunoCONTROL CHLAMYDIA pneumoniae IgA
- SERION immunoCONTROL CHLAMYDIA trachomatis IgG
- SERION immunoCONTROL CHLAMYDIA trachomatis IgM
- SERION immunoCONTROL RUBELLA-VIRUS IgM
- SERION immunoCONTROL TOXOPLASMA gondii IgM
- SERION immunoCONTROL TORCH IgG

**Date:** 2019-03-28

**Notified Body**



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**Registration No.:** HL 60135571 0001  
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**Manufacturer:** Institut Virion\Serion GmbH  
Friedrich-Bergius-Ring 19  
97076 Würzburg  
Deutschland

**Products included:**

- CFT CYTOMEGALOVIRUS reagents
- CFT TOXOPLASMA GONDII reagents
- CFT CHLAMYDIA reagents

**Date:** 2019-03-28

**Notified Body**



*D. Wiedemuth*  
**Dipl.-Ing. (FH) D. Wiedemuth**