Highlights of Immunomat™

- **SERION ELISA Analyzer** for medium to high throughput applications
- Validated for **antibody detection** in serum, plasma or cerebrospinal fluid (CSF), for **avidity determination** and **antigen detection** with **SERION ELISA immunoassays**
- **Short loading times** by **barcode identification** of samples, reagents and microtiter plates
- Processing of **up to 16 different assays per plate**
- **Reload function** for patient samples, reagents and microtiter plates
- **2D hand barcode scanner** for **parameters of quality control certificates**
- **Multishot dispenser function** and **memory function for tip racks**
- **Optimize function** for scheduling for an **efficient workload** of the instrument
- **Clot detection** and **bubble kill function** guarentee **walk-away functionality**
- **Level sensors for fluid containers** with **automated warning** in case of **lack of reagents or filled waste container**
- **Easy access to buffers and reagents**
- Fast and **quantitative evaluation** of SERION ELISA immunoassays
- **Parameter- or patient-orientated result reports**
- **Listing of test reagents**
- **Import/export function for reagents**
- Integrated **reports for quality controls** of standards and controls
- **Bi-directional connection to laboratory software systems** via ASTM interface

Order Information of Immunomat™ and Lab Ware

Immunomat™	**Order Nr.:**	**VT 020**	
SERION Clean, cleaning solution, 500 ml, 5 x conc.	Order Nr.:	VT 125	
Deep well microtiter plates, 50 pieces	Order Nr.:	VT 124	6 pd
Pipetting tips, 300 µl, 18 x 960 tips	Order Nr.:	VT 111	
Pipetting tips, 1100 µl, 10 x 960 tips	Order Nr.:	VT 112	
Plastic bottles, white, with cap, 35 ml, 100 pieces	Order Nr.:	VT 113	
Plastic bottles, yellow, with cap, 35 ml, 100 pieces	Order Nr.:	VT 114	
Plastic bottles, white, with cap, 50 ml, 100 pieces	Order Nr.:	VT 115	
Glas bottles, with cap, 2.5 ml, 323 pieces	Order Nr.:	VT 116	
Glas bottles, with cap, 2.5 ml, 30 pieces	Order Nr.:	VT 116-30	
Waste bags, 10 pieces	Order Nr.:	VT 051	

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Germany

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Fax: +49 (0)931 3045-100
dialog@virion-serion.de
www.virion-serion.com

Certificate transfer

20250630
Phone: +49 931 / 30 45 0
Mail: regulatory@virion-serion.de

Dear Sir or Madam,

IVDR certificate

In February 2025 we have informed you about the achievement of the IVDR certification for our class B and C products of the following product groups:

- SERION ELISA *classic* (ESRxxx)
- SERION ELISA *antigen* (ESR200)
- SERION ELISA *control* (BCxxx)
- SERION *immuno*CONTROL (ICxxx)
- SERION ELISA AI *control* (CLSxxx)
- SERION ELISA Avidity Control (BRxxxAVID)
- SERION ELISA Avidity Reagent (BxxxAVID)
- SERION RF Absorbent (Z200)

It is certified that requirements according to REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III are fulfilled for the covered products of class B as well as class C products.

With this mailing we would like to inform you that the current IVDR certificates are being transferred to another Notified Body, TÜV Süd (number 0123).

The IVDR certificate will be issued by TÜV Süd with the corresponding number 0123. Please note that the content of the certificate remains unchanged and therefore the certificate transfer does not affect the certification status of our products. A change will apply for the labelling of the devices as the number of the new Notified Body will be implemented for labels, Instructions for Use (IFU) and Declarations of Conformity (DoC).

The effective date for certificate transfer is **June 30, 2025**.

The certificate is shared on our homepage here: Quality and Certificates | Virion\Serion (virion-serion.de)

From July 1, 2025, newly produced product lots will be labelled with the new number 0123.

Updated DoCs, IFUs and labels will be made available upon request after July 1, 2025. Please let us know which information is required from your side.

The change of labelling will be implemented successively for the individual products and depends on the production schedule. Within a transition period of 18 months all products will carry the new labelling.

The CE with number of Notified Body will be removed from component labels of device components as this is not mandatory for components.

EN ISO 13485 certificate

The EN ISO 13485 certificate has been transferred to TÜV Süd (number 0123) and validity date is from 2025-05-30. The certificate number is Q5 131304 0001 Rev. 00. The scope has been extended regarding the instruments for infection diagnostics.

The certificate is shared on our homepage here: Quality and Certificates | Virion\Serion (virion-serion.de)

If you have any further questions or comments, don´t hesitate to contact us.

We thank you for your understanding and cooperation.

With best regards,

Institut Virion\Serion GmbH

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Phone +49 931 3045 0 **Fax** +49 931 3045 100 **Mail** diagnostics@virion-serion.de **Web** www.virion-serion.de

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 131304 0003 Rev. 00

Manufacturer:

Institut Virion\Serion GmbH
Friedrich-Bergius-Ring 19
97076 Würzburg
GERMANY

SRN Manufacturer - DE-MF-000007582

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V13 131304 0003 Rev. 00

Report No.: 713371585
Valid from: 2025-07-01
Valid until: 2029-05-15

Marta Carnielli
Head of Certification IVD

Issue date: 2025-07-01

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 131304 0003 Rev. 00

Classification:	Class B
Device Group:	IVR 0503 - Infectious agent detection: Presence of, or exposure to an infectious agent
Intended Purpose:	Devices intended to be used to detect the presence of, or exposure to an infectious agent
Classification:	Class C
Device Group:	W0105 + IVP 3007 - Infectious diseases
Intended Purpose:	IVD Reagents for Infectious diseases
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Rev.	Dated	Report	Description
00	2025-07-01	713371585	Initial issuance

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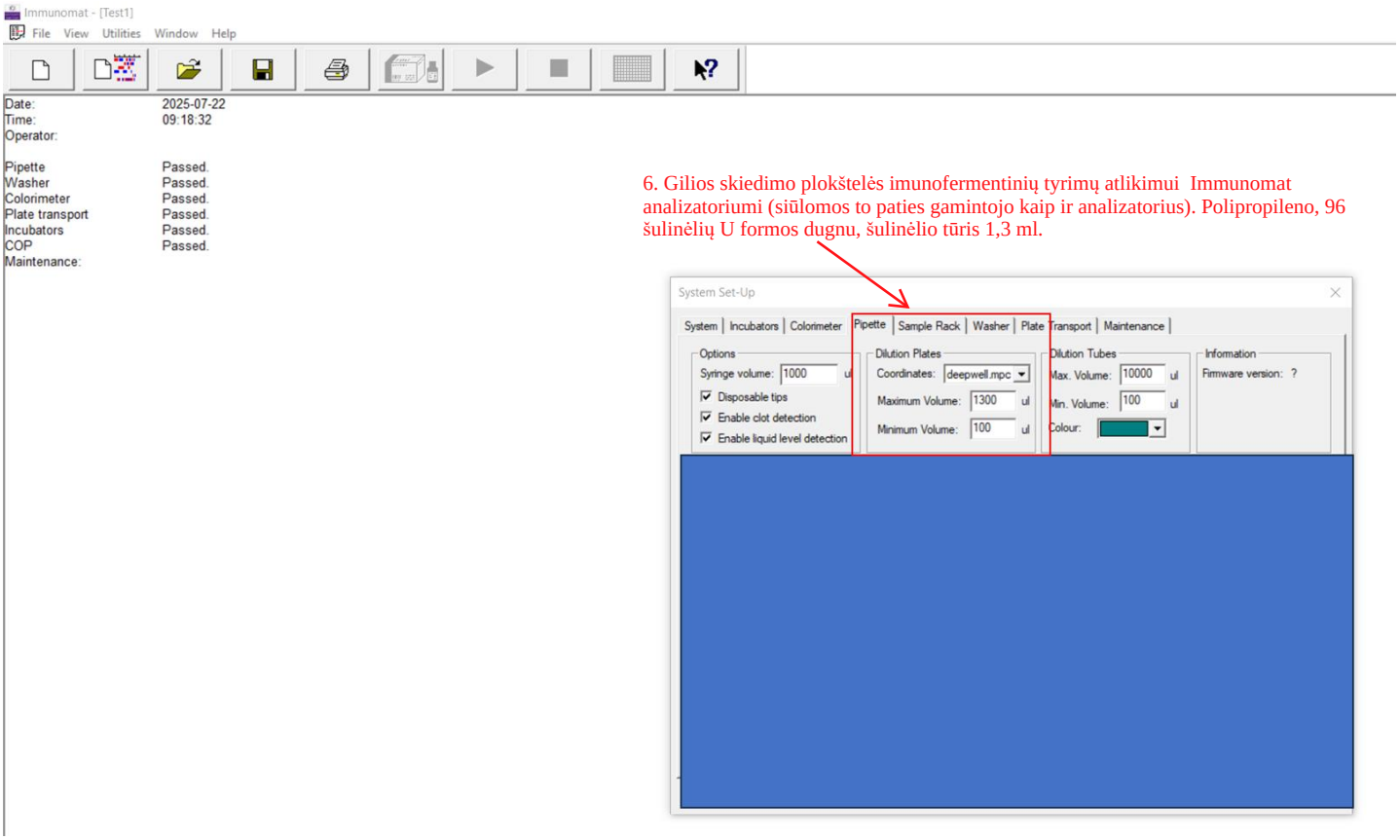
TÜV®



6. Gilios skiedimo plokštelės imunofermentinių tyrimų atlikimui Immunomat analizatoriumi (siūlomos to paties gamintojo kaip ir analizatorius). Polipropileno, 96 šulinėlių U formos dugnu, šulinėlio tūris 1,3 ml.