

EU Certificate

Quality Management System REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices Annex IX Chapters I and III

Registration No.: HX 1624072-1
Manufacturer: Seramun Diagnostica GmbH
Spreenhagener Str. 1
15754 Heidensee
Germany

EUDAMED Single
Registration No.: DE-MF-000026029

Products: Products of class B:

INFECTIOUS DISEASES

IVR 0503: Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

W01050104 - HELICOBACTER PYLORI

The Notified Body hereby declares that the requirements of Annex IX, Chapter I of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4 is required before placing them on the market.

If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market.

If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market.

Report No.: 1101862-270
Effective date: 2025-10-30
Expiry date: 2029-10-08
Issue date: 2025-10-30



DR. Volker Schlueter
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This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

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Products: IMMUNOCHEMISTRY (IMMUNOLOGY)

IVR 0602: Devices intended to be used for screening,
determination or monitoring of physiological markers for a
specific disease

W01021004 - VASCULITIS

Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-10-09
1	Amended for the scope IVR 0602 (W01021004)	2025-10-30