

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Scope: Design and development, manufacture, installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics



The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14



D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

No.	Facility	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and development and manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for instruments for in vitro diagnostics
/02	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design, development, manufacture and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics
/03	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design, development, manufacture, service and distribution of immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents and instruments / software for in vitro diagnostics

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14



D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

- | | | |
|-----|--|--|
| /04 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Sonnenberg 9
23627 Groß Grönau
Germany | Design, development and manufacture of immunofluorescence test systems, molecular diagnostic / genetic test systems and, test systems for the determination of infectious agents for in vitro diagnostics |
| /05 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Born 24
23627 Groß Grönau
Germany | Design and development of software for in vitro diagnostics |
| /06 | EUROIMMUN
Medizinische Labordiagnostika AG
Im Kreppel 1
02747 Herrnhut
Germany | Manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems and test systems for the determination of infectious agents for in vitro diagnostics |
| /07 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Pließnitztal 1
02748 Bernstadt
Germany | Manufacture of immunobiochemical test systems, test systems for the determination of infectious agents and instruments for in vitro diagnostics |

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14



D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

- | | | |
|-----|--|--|
| /08 | EUROIMMUN
Medizinische Labordiagnostika AG
Schloßstr. 11
91257 Pegnitz
Germany | Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic |
| /09 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Flugplatz 4
23560 Lübeck
Germany | Installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software for in vitro diagnostics |
| /10 | EUROIMMUN
Medizinische Labordiagnostika AG
Gewerbestr. 19
23942 Dassow
Germany | Manufacture of sheet metal and other components for instruments for in vitro diagnostics |

Report No.: 3313978-90

Effective date: 2020-05-19

Expiry date: 2023-05-18

Issue date: 2020-05-14



D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

