

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 immuno-biochemical 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.: 1130650-10
Effective date: 2023-05-19
Expiry date: 2026-05-18
Issue date: 2023-05-11



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



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EN ISO 13485:2016**

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Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and development and manufacture of immuno-biochemical 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	c/o EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design and development, manufacture and distribution of immuno-biochemical 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	c/o EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design and development, manufacture, service and distribution of immuno-biochemical test systems, immunofluorescence test systems and instruments / software for in vitro diagnostics

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Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following:

- | | | |
|-----|------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| /04 | c/o EUROIMMUN
Medizinische Labordiagnostika AG
Am Sonnenberg 9
23627 Groß Grönau
Germany | Manufacture of immunofluorescence test systems for in vitro diagnostics |
| /05 | c/o EUROIMMUN
Medizinische Labordiagnostika AG
Am Born 24
23627 Groß Grönau
Germany | Design and development of software for in vitro diagnostics |
| /06 | c/o EUROIMMUN
Medizinische Labordiagnostika AG
Im Kreppel 1
02747 Herrnhut
Germany | Manufacture of immuno-biochemical test systems and immunofluorescence test systems for in vitro diagnostics |
| /07 | c/o EUROIMMUN
Medizinische Labordiagnostika AG
Am Pließnitztal 1
02748 Bernstadt
Germany | Manufacture of immuno-biochemical test systems and instruments for in vitro diagnostics |

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Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following:

- | | | |
|-----|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /08 | c/o 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 | c/o EUROIMMUN
Medizinische Labordiagnostika AG
Am Flugplatz 4
23560 Lübeck
Germany | Design and development, installation, service and distribution of immuno-biochemical 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 | c/o EUROIMMUN
Medizinische Labordiagnostika AG
Gewerbestr. 19
23942 Dassow
Germany | Manufacture of sheet metal and other components for instruments for in vitro diagnostics |

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D. Wiedemuth

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Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following:

/11 c/o EUROIMMUN
Medizinische Labordiagnostika AG
Am Berzdorfer See 7
02829 Markersdorf
Germany

Warehousing of immuno-biochemical test systems and instruments for in vitro diagnostics

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