



Product Service

Certificate

No. Q5 056540 0024 Rev. 04

Holder of Certificate: **EIKEN CHEMICAL CO., LTD.**4-19-9 Taito, Taito-ku
Tokyo
110-8408 JAPAN**Certification Mark:****Scope of Certificate:**

Design and Development, Production and Distribution of IVD reagents and related Calibrators and Controls for Clinical Chemistry, Immunochemistry, Microbiology, and Infection diseases. Production and Distribution of IVD Generic Use Consumables for sample collection and storage for Microbiology (swab, container) and Infection diseases (swab). Design and Development, Production, Distribution, Installation, Servicing of IVD Instruments and IVD Generic Use Consumables for sample collection and storage for Immunochemistry and Infection diseases (container).

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5_056540_0024_Rev.04

Report No.: JN73232263**Valid from:** 2024-06-25**Valid until:** 2027-06-24**Date,** 2024-06-19

Christoph Dicks

Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

EIKEN CHEMICAL CO., LTD.

4-19-9 Taito, Taito-ku, Tokyo, 110-8408 JAPAN

Distribution of IVD reagents and related Calibrators and Controls for Clinical Chemistry, Immunochemistry, Microbiology, and Infection diseases. Distribution of IVD Generic Use Consumables for sample collection and storage for Microbiology (swab, container) and Infection diseases (swab). Design and Development, Production, Distribution, installation and Servicing of IVD Instruments and IVD Generic Use Consumables for sample collection and storage for Immunochemistry and Infection diseases (container).

EIKEN CHEMICAL CO., LTD. Nogi Plant

143 Nogi, Nogi-machi, Shimotsuga-gun, Tochigi, 329-0114 JAPAN

Design and Development, Production and Distribution of IVD reagents and related Calibrators and Controls for Clinical Chemistry, Immunochemistry, Microbiology, and Infection diseases. Production and Distribution of IVD Generic Use Consumables for sample collection and storage for Microbiology (swab, container) and Infection diseases (swab). Distribution of IVD Generic Use Consumables for sample collection and storage for Immunochemistry (container).

EIKEN CHEMICAL CO., LTD. Nasu Plant

1381-3 Shimoishigami, Otawara-shi, Tochigi, 324-0036 JAPAN

Production and Distribution of IVD reagents and related Calibrators and Controls for Clinical Chemistry, Immunochemistry, Microbiology and Infection diseases.

EIKEN CHEMICAL CO., LTD. Europe Office

Burgemeester Haspelslaan 25, 1181 NB Amstelveen, THE NETHERLANDS

Marketing for IVD Reagents and related Calibrators and Controls for Clinical Chemistry, Immunochemistry, Microbiology, and Infection diseases. Training of Installation and Maintenance for IVD Analyzers and IVD Generic Use Consumables for sample collection and storage for Immunochemistry and Infection diseases (container).

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