ZERTIFIKAT ◆ 认证证书 ◆ CERTIFICATE ◆ 認証書 ◆ CERTIFICATO ◆ 인증서 ◆ CERTIFICADO

CERTIFICATE

No. QS5 056540 0027 Rev. 00

Certificate Holder: **EIKEN CHEMICAL CO., LTD.**
4-6 Kanda Surugadai
Chiyoda-ku, Tokyo
101-0062 JAPAN

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In-Vitro Diagnostic Reagents, Calibrators and Control Materials for Microbiological Testing, Clinical Chemical Testing, Urine Testing, Immunochemical Testing, Serological Testing and Nucleic Acid Testing, Media and Reagents for Microbiological Testing, Specimen Receptacles and Apparatus for Clinical, Food and Environmental Testing and Reagents for Food and Environmental Analysis and Animal and Plant Diagnosis; Design, Distribution, Installation and Servicing of IVD Analyzers and Related Devices for Specimen Collection**

COPY

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **56540_UCB_Transfer**

Effective Date: **2026-09-30**

Expiry Date: **2027-07-30**

Date of Issue: 2026-10-16

(Sofia Epshtein Elbrus)
Director, US Certification Body, MHS

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CERTIFICATE

No. QS5 056540 0027 Rev. 00

Facility(ies):

EIKEN CHEMICAL CO., LTD.
4-6 Kanda Surugadai, Chiyoda-ku, Tokyo, 101-0062
JAPAN

Facility Scopes:

Distribution of In-Vitro Diagnostic Reagents, Calibrators and Control Materials for Microbiological Testing, Clinical Chemical Testing, Urine Testing, Immunochemical Testing, Serological Testing and Nucleic Acid Testing, Media and Reagents for Microbiological Testing, Specimen Receptacles and Apparatus for Clinical, Food and Environmental Testing and Reagents for Food and Environmental Analysis and Animal and Plant Diagnosis; Design, Distribution, Installation and Servicing of IVD Analyzers and Related Devices for Specimen Collection

COPY

Facility(ies):

EIKEN CHEMICAL CO., LTD.
Nogi Plant, 143 Nogi, Nogi-machi, Shimotsuga-gun,
Tochigi, 329-0114 JAPAN

Facility Scopes:

Design and Development, Production and Distribution of In-Vitro Diagnostic Reagents, Calibrators and Control Materials for Microbiological Testing, Clinical Chemical Testing, Urine Testing, Immunochemical Testing, Serological Testing and Nucleic Acid Testing, Media and Reagents for Microbiological Testing, Specimen Receptacles and Apparatus for Clinical, Food and Environmental Testing and Reagents for Food and Environmental Analysis and Animal and Plant Diagnosis; Distribution of Related Devices for Specimen Collection

Date of Issue: 2026-10-16

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CERTIFICATE

No. QS5 056540 0027 Rev. 00

Facility(ies):

EIKEN CHEMICAL CO., LTD.
Nasu Plant, 1381-3 Shimoishigami, Otawara-shi,
Tochigi, 324-0036 JAPAN

Facility Scopes:

Production and Distribution of In-Vitro Diagnostic Reagents, Calibrators and Control Materials for Microbiological Testing, Clinical Chemical Testing, Urine Testing, Immunochemical Testing, Serological Testing and Nucleic Acid Testing, Media and Reagents for Microbiological Testing, Specimen Receptacles and Apparatus for Clinical, Food and Environmental Testing and Reagents for Food and Environmental Analysis and Animal and Plant Diagnosis

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