



Management Service

CERTIFICATE

Certificate Registration No.: 12 100 26393 TMS / Order No.: 73590601

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that the organization

EIKEN CHEMICAL CO., LTD.

4-6, Kanda, Surugadai, Chiyoda-ku,
Tokyo 101-0062
Japan

for the scope

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

including the sites see enclosure

has established and applies a Quality Management System.

An audit was performed and has furnished proof
that the requirements according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from 2025-12-29 until 2027-07-30.

Fred Wenke
Head of Certification Body
Munich, 2025-12-30

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ENCLOSURE OF CERTIFICATE

Certificate Registration No.: 12 100 26393 TMS / Order No.: 73590601

certificate holder:

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

at the sites	scope
EIKEN CHEMICAL CO., LTD. 4-6, Kanda, Surugadai, Chiyoda-ku, Tokyo 101-0062 Japan	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.
EIKEN CHEMICAL CO., LTD. 1381-3, Shimoishigami, Otawara-shi, Tochigi 324-0036 Japan	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.
EIKEN CHEMICAL CO., LTD. 143 Nogi, Nogi-machi, Shimotsuga-gun, Tochigi 329-0114 Japan	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.

Fred Wenke
Head of Certification Body
Munich, 2025-12-30

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