



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.**  
**(Head Office)**

Yamaguchi Bldg. 7, 4-19-9 Taito, Taito-ku,  
Tokyo 110-8408  
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 **2024-07-31** until **2027-07-30**.

Fred Wenke  
Head of Certification Body  
Munich, 2024-07-08

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CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

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CERTIFICADO



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認證證書



CERTIFICATE



ZERTIFIKAT

# ENCLOSURE OF CERTIFICATE

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

certificate holder:

**EIKEN CHEMICAL CO., LTD.**  
**(Head Office)**  
**Yamaguchi Bldg. 7, 4-19-9 Taito, Taito-ku,**  
**Tokyo 110-8408**  
**Japan**

at the sites	scope
<b>EIKEN CHEMICAL CO., LTD.</b> (Head Office) Yamaguchi Bldg. 7, 4-19-9 Taito, Taito-ku, Tokyo 110-8408 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.
<b>EIKEN CHEMICAL CO., LTD.</b> (Nasu Plant) 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.
<b>EIKEN CHEMICAL CO., LTD.</b> (Nogi Plant) 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.
<b>EIKEN CHEMICAL CO., LTD.</b> (Europe Office) Burgemeester Haspelslaan 25 1181 NB Amstelveen Netherlands	Support of local distributors sales promotion for 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. Support of local distributors performing installation and technical support for IVD Analyzers and related products.

Fred Wenke  
Head of Certification Body  
Munich, 2024-07-08

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