



# Certificate

No. Q5 056540 0024 Rev. 03

**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 for Microbiological testing, Clinical chemical testing, Urine testing, Immunochemical testing, Serological testing and Nucleic acid testing. Production and Distribution of Swabs and Specimen containers for Microbiological testing. Design, Distribution, Installation and Servicing of IVD Analyzers and related devices for specimen collection.

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 and certification regulation of 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. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_056540_0024_Rev_03)

**Report No.:** JN2036926

**Valid from:** 2023-07-31  
**Valid until:** 2024-06-24

**Date,** 2023-07-31

Christoph Dicks  
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT

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No. Q5 056540 0024 Rev. 03

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **EIKEN CHEMICAL CO., LTD.**  
**4-19-9 Taito, Taito-ku, Tokyo, 110-8408 JAPAN**

Distribution of IVD reagents for Microbiological testing,  
Clinical chemical testing, Urine testing, Immunochemical  
testing, Serological testing and Nucleic acid testing.  
Distriburion of Swabs and Specimen containers for  
Microbiological testing.  
Design, Distribution, Installation and Servicing of IVD  
Analyzers and related devices for specimen collection.

**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 for Microbiological testing, Clinical chemical testing,  
Urine testing, Immunochemical testing, Serological testing  
and Nucleic acid testing.  
Production and Distriburion of Swabs and Specimen  
containers for Microbiological testing.  
Distribution of related devices for specimen collection.

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

Design and Development, and Production of IVD reagents for  
Microbiological testing, Clinical chemical testing, Urine  
testing, Immunochemical testing, Serological testing and  
Nucleic acid testing.

**EIKEN CHEMICAL CO., LTD. Europe Office**  
**Burgemeester Haspelslaan 25, 1181 NB Amstelveen, THE**  
**NETHERLANDS**

The provision of Marketing for IVD Reagents for Microbiological  
testing, Clinical chemical testing, Urine testing, Immunochemical  
testing, Serological testing and Nucleic acid testing.  
The provision of Training of installation and Maintenance  
Servicing for IVD Analyzers and related products.