



Certificate

No. Q5 056540 0024 Rev. 02

Holder of Certificate: **EIKEN CHEMICAL CO., LTD.**
Head Office
Yamaguchi Bldg. 7
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. 02

Report No.: JN1607323

Valid from: 2021-06-25
Valid until: 2024-06-24

Date, 2021-06-14

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

Certificate

No. Q5 056540 0024 Rev. 02

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. Head Office
Yamaguchi Bldg. 7, 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.

-/-

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT