



Product Service

Certificate

No. Q5 054403 0032 Rev. 04

Holder of Certificate: **KANTO CHEMICAL Co., Inc.**
East Muromachi Mitsui BLDG., 2-1
Nihonbashi Muromachi 2-chome, Chuo-ku
Tokyo
103-0022 JAPAN

Certification Mark:



Scope of Certificate: **Design and development, production, and Distribution of in vitro diagnostic reagents, and calibrator and control materials for clinical chemistry, immunochemistry, and microbiology.**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 054403 0032 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_054403_0032_Rev_04)

Report No.: JV200350011832

Valid from: 2026-01-01
Valid until: 2028-12-31

Date, 2025-10-20

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 054403 0032 Rev. 04

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **KANTO CHEMICAL Co., Inc.**
East Muromachi Mitsui BLDG., 2-1, Nihonbashi Muromachi 2-
chome, Chuo-ku, Tokyo, 103-0022 JAPAN

Design and Development of in vitro diagnostic reagents, and
calibrator and control materials for clinical chemistry,
immunochemistry, and microbiology

KANTO CHEMICAL Co., Inc. Isehara Factory
21, Suzukawa Isehara-shi, Kanagawa-ken, 259-1146 JAPAN

Design and development, production and Distribution of in vitro
diagnostic reagents, and calibrator and control materials for clinical
chemistry, immunochemistry, and microbiology.

-/-