



Certificate

No. Q5 055720 0003 Rev. 05

Holder of Certificate: **Denka Co., Ltd.**
1359-1 Kagamida, Kigoshi
Gosen-shi, Niigata
959-1695 JAPAN

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In vitro Diagnostic Reagents for Clinical Chemistry, Immunochemistry and Infectious Disease. Production and Distribution of In vitro Diagnostic Instruments for Immunochemistry. Provision of Service for Production (Labelling) and Distribution of Sterile Medical Devices (Sterilized Swabs)**

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 055720 0003 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_055720_0003_Rev._05)

Report No.: **JN2052206**

Valid from: **2023-07-01**

Valid until: **2026-06-30**

Date, 2023-06-30



Christoph Dicks
Head of Certification/Notified Body

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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): **Denka Co., Ltd.**
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Design and Development, Production and Distribution of
In vitro Diagnostic Reagents for Clinical Chemistry,
Immunochemistry and Infectious Disease.
Production and Distribution of In vitro Diagnostic Instruments for
Immunochemistry.
Provision of Service for Production (Labelling) and Distribution of
Sterile Medical Devices (Sterilized Swabs)

Denka Co., Ltd. Head Office
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo,
103-8338 JAPAN

Management of In vitro Diagnostic Reagents for Clinical
Chemistry, Immunochemistry and Infectious Disease.
Management of In vitro Diagnostic Instruments for
Immunochemistry.
Management of Sterile Medical Devices (Sterilized Swabs)

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