



Certificate

No. Q5 055720 0003 Rev. 04

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
Clinical Chemistry, Immunological,
Bacterial and Viral Diagnostic Reagents.
Production and Distribution of
Sterilized Swabs and Densitometry Analyzers.**

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. 04

Report No.: **JN1660007**

Valid from: **2021-09-13**
Valid until: **2023-06-30**

Date, **2021-09-13**



Christoph Dicks
Head of Certification/Notified Body

Certificate

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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.
1359-1 Kagamida, Kigoshi, Gosen-shi, Niigata, 959-1695
JAPAN

**Design and Development, Production and Distribution of
Clinical Chemistry, Immunological, Bacterial and Viral
Diagnostic Reagents.
Production and Distribution of Sterilized Swab and
Densitometry Analyzer**

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

**Management of Clinical Chemistry, Immunological, Bacterial
and Viral Diagnostic Reagents, Sterilized Swab and
Densitometry Analyzer**

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