



Product Service

# Certificate

No. Q5 055720 0003 Rev. 02

**Holder of Certificate:** **Denka Co., Ltd.**  
1-1, Nihonbashi-Muromachi 2-chome  
Chuo-ku, Tokyo  
103-8338 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). See also notes overleaf.

**Report No.:** **JN1465982**

**Valid from:** **2020-07-01**

**Valid until:** **2023-06-30**

**Date,** **2020-06-25**

**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.  
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo,  
103-8338 JAPAN

Denka Co., Ltd. Kagamida Factory  
1359-1 Kagamida, Kigoshi, Gosen-shi, Niigata,  
959-1695 JAPAN

Denka Co., Ltd. Tokyo Medical Branch  
12-7 Nihonbashi-Koamicho, Chuo-ku, Tokyo,  
103-0016 JAPAN

Denka Co., Ltd. Kanetsu Medical Branch  
1-9-6 Sakuragicho, Omiya-ku, Saitama-shi, Saitama,  
330-0854 JAPAN

Denka Co., Ltd. Osaka Medical Branch  
4-7-18 Nishi-nakajima, Yodogawa-ku, Osaka-shi, Osaka,  
532-0011 JAPAN

Denka Co., Ltd. Sapporo Medical Sales Office  
9-1-15 Minami 1-jo Nishi, Chuo-ku, Sapporo-shi, Hokkaido,  
060-0061 JAPAN

Denka Co., Ltd. Sendai Medical Sales Office  
4-2-16 Chuo, Aoba-ku, Sendai-shi, Miyagi, 980-0021 JAPAN

Denka Co., Ltd. Nagoya Medical Sales Office  
49-1 Inouecho, Chikusa-ku, Nagoya-shi, Aichi,  
464-0026 JAPAN

Denka Co., Ltd. Hiroshima Medical Sales Office  
1-7-11 Hikarimachi, Higashi-ku, Hiroshima-shi, Hiroshima,  
732-0052 JAPAN

Denka Co., Ltd. Fukuoka Medical Sales Office  
8-20 Hakataekichuougai, Hakata-ku, Fukuoka-shi, Fukuoka,  
812-0012 JAPAN

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