



# Certificate

No. Q5 058789 0026 Rev. 03

**Holder of Certificate:** **Minaris Medical Co., Ltd.**  
1-8-10, Harumi  
Chuo-ku, Tokyo  
104-6004 JAPAN

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of Biochemical and Immunological Products for In Vitro Diagnosis and the related Calibrators and Accessories. Design and Development, Production, Distribution, Installation and Servicing of Immunological Auto Analysis Equipment**

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 058789 0026 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5 058789 0026 Rev. 03)

**Report No.:** **JN1654901**

**Valid from:** **2021-11-01**

**Valid until:** **2024-10-31**

**Date,** **2021-10-27**



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):** **Minaris Medical Co., Ltd.**  
**1-8-10, Harumi, Chuo-ku, Tokyo, 104-6004 JAPAN**

Design and Development of Biochemical and Immunological  
Products for In Vitro Diagnosis and the related Calibrators and  
Accessories.

**Minaris Medical Co., Ltd. Fuji Plant**  
**600-1 Minami-ishiki, Nagaizumi-cho, Sunto-gun,**  
**Shizuoka-ken, 411-0932 JAPAN**

Design and Development, Production and Distribution of  
Biochemical and Immunological Products for In Vitro  
Diagnosis and the related Calibrators and Accessories.  
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Distribution, Installation and Servicing of  
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