



# Certificate

No. Q5 078509 0005 Rev. 03

**Holder of Certificate:** **YOKOWO CO., LTD.**  
JR KANDA MANSEIBASHI BUILDING 14F  
1-25 KANDASUDACHO  
CHIYODA-KU, TOKYO  
101-0041 JAPAN



**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of Sterile Transseptal needle, Sterile Catheter and Sterile Guide wire. Production and Distribution of Parts and Semi-finished products for Guide wire.**

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 078509 0005 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5 078509 0005 Rev. 03)

**Report No.:** JN1485051814

**Valid from:** 2024-03-05  
**Valid until:** 2027-03-04

**Date,** 2024-02-29



Christoph Dicks  
Head of Certification/Notified Body

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**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):** **YOKOWO CO., LTD.**  
**JR KANDA MANSEIBASHI BUILDING 14F, 1-25**  
**KANDASUDACHO, CHIYODA-KU, TOKYO, 101-0041 JAPAN**

Distribution of Sterile Transseptal needle, Sterile Catheter and  
Sterile Guide wire.

Distribution of Parts and Semi-finished products for Guide wire.

**YOKOWO CO., LTD. TOMIOKA PLANT**  
**1112 KANOHARA, TOMIOKA-SHI, GUNMA, 370-2495 JAPAN**

Design and Development, Production and Distribution of Sterile  
Transseptal needle, Sterile Catheter and Sterile Guide wire.  
Production and distribution of Parts and Semi-finished products for  
Guide wire.

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