



# Certificate

No. Q6 071551 0006 Rev. 00

**Holder of Certificate:** **Kaneko MediX Inc.**  
342 Tsukinukizawa  
Nasushiobara-shi, Tochigi  
329-2703 JAPAN

**Facility(ies):** **Kaneko MediX Inc.**  
342 Tsukinukizawa, Nasushiobara-shi, Tochigi,  
329-2703 JAPAN

**Kaneko MediX Inc. Tsukinukizawa Factory**  
286-3 Tsukinukizawa, Nasushiobara-shi, Tochigi,  
329-2703 JAPAN

**Kaneko MediX Inc. Nogi Factory**  
163-335 Shinnan, Nasushiobara-shi, Tochigi,  
329-2704 JAPAN

**Certification Mark:**



**Scope of Certificate:** **Production and Distribution of Needles,  
Cannulas and Cut Tubes for Medical Devices**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), 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:Q6 071551 0006 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q6 071551 0006 Rev. 00)

**Report No.:** **JN1549982**

**Valid from:** **2020-11-22**

**Valid until:** **2023-11-21**

**Date,** **2020-11-18**



Christoph Dicks  
Head of Certification/Notified Body