



Certificate

No. Q8 071551 0007 Rev. 00

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

Certification Mark:



Scope of Certificate: **The Provision of Manufacturing Services for Needles, Cannulas and Cut Tubes as metal components for Nonactive Medical Devices**

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:Q8 071551 0007 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q8_071551_0007_Rev_00)

Report No.: JN2096556

Valid from: 2023-11-22
Valid until: 2026-11-21

Date, 2023-11-10



Christoph Dicks
Head of Certification/Notified Body

Certificate

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

The Provision of Manufacturing Services for Needles,
Cannulas and Cut Tubes as metal components for Nonactive
Medical Devices

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

The Provision of Manufacturing Services for Needles,
Cannulas and Cut Tubes as metal components for Nonactive
Medical Devices

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

The Provision of Manufacturing Services for Needles,
Cannulas and Cut Tubes as metal components for Nonactive
Medical Devices

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