



# Certificate

No. Q5 024736 0069 Rev. 02

Holder of Certificate:

**KANEKA**

**KANEKA Corporation**

3-18, 2-Chome, Nakanoshima, Kita-ku  
Osaka-city, OSAKA  
530-8288 JAPAN

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Medical Device for Selective Blood or Plasma Component Adsorption, Catheter Intervention, Surgical or Neurosurgical Drainage, Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation / Harvesting, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology.  
Production and Distribution of Blood Flowmeter and Inflation Device.  
Distribution of Plasma Separator, Blood Tubing Lines and Apheresis Unit.  
Design and Development, Production and Distribution of In-vitro Diagnostic Products for Genetic-testing.

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 024736 0069 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 024736 0069 Rev. 02)

Report No.:

**JN1459484**

Valid from:

**2021-03-01**

Valid until:

**2023-08-31**

Date,

**2021-02-10**



Christoph Dicks

Head of Certification/Notified Body

# Certificate

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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):** **KANEKA Corporation**  
**3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA,**  
**530-8288 JAPAN**

Design and Development, Production and Distribution of Medical  
Devices for Selective Blood or Plasma Component Adsorption,  
Catheter Intervention, Surgical or Neurosurgical Drainage,  
Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation /  
Harvesting, Endoscopic Intervention, Ophthalmology, Vascular /  
Neurovascular Embolization and Cardiac Electrophysiology  
Production and Distribution of Blood Flowmeter and Inflation  
Device

Distribution of Plasma Separator, Blood Tubing Lines and  
Apheresis Unit  
Design and Development, Production and Distribution of In-vitro  
Diagnostic Products for Genetic-testing

**KANEKA Corporation Osaka Plant**  
**5-1-1, Torikai-Nishi, Settsu-city, OSAKA, 566-0072 JAPAN**

Design and Development, Production and Distribution of Medical  
Devices for Selective Blood or Plasma Component Adsorption,  
Catheter Intervention, Surgical or Neurosurgical Drainage,  
Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation /  
Harvesting, Endoscopic Intervention, Ophthalmology and Vascular  
/ Neurovascular Embolization  
Production and Distribution of Blood Flowmeter and Inflation  
Device

Distribution of Plasma Separator, Blood Tubing Lines and  
Apheresis Unit  
Production and Distribution of In-vitro Diagnostic Products for  
genetic-testing

**KANEKA Corporation Takasago Plant**  
**1-8, Miyamae-cho, Takasago-cho, Takasago, Hyogo, 676-8688**  
**JAPAN**

Design and Development, Production and Distribution of In-vitro  
Diagnostic Products for genetic-testing

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## Facility(ies):

**KANEKA Medix Corporation Kanagawa Plant**  
225-1, Aza Deguchi, Yamakita, Yamakita-machi,  
Ashigara-Kami-gun, KANAGAWA, 258-0113 JAPAN

Production and Distribution of Medical Devices for Catheter Intervention, Surgical or Neurosurgical Drainage, Cerebral Shunt, Vacuum Extraction Delivery, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology

**KANEKA Medix Corporation Osaka Office**  
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA,  
530-8288 JAPAN

Sales Office

**KANEKA MEDICAL VIETNAM CO., LTD.**  
35 VSIP Street 6, Vietnam - Singapore Industrial Park,  
An Phu Ward, Thuan An City, Binh Duong Province, VIETNAM

Production of Catheter Intervention, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology

**KANEKA Corporation Tokyo Office**  
12-32, 1-Chome, Akasaka, Minato-ku, Tokyo, 107-6028 JAPAN

Sales Office

**KANEKA Medix Corporation Tokyo Office**  
12-32, 1-Chome, Akasaka, Minato-ku, Tokyo, 107-6028 JAPAN

Sales Office

**KANEKA Medix Corporation Tokyo Logistics Center**  
3-2-52, Yashio, Shinagawa-ku, Tokyo, 140-0003 JAPAN

Distribution of all products

**Kaneka Medical Tech Corporation Ina Factory**  
7108-1 Nishiminowa, Ina-shi, Nagano, 399-4501 JAPAN

Production and Distribution of Medical Devices for Endoscopic Intervention and Ophthalmology

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## Facility(ies):

**Kaneka Medical Tech Corporation Okaya Factory**  
**2-6-16 Kohan, Okaya-shi, Nagano, 394-0034 JAPAN**

Design and Development, Production and Distribution of Medical  
Devices for Endoscopic Intervention, Ophthalmology and Cardiac  
Electrophysiology

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