



Product Service

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

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

No. Q5 024736 0069 Rev. 02

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

Certificate

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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

Certificate

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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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