



Certificate

No. Q5 024736 0069 Rev. 00

Holder of Certificate:

カネカ

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). See also notes overleaf.

Report No.:

JNQ235032972

Valid from:

2018-09-06

Valid until:

2020-08-31

Date,

2018-09-06

Stefan Preiß

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

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

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

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

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

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

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

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

River Seiko Corporation Ina Factory
7108-1 Nishiminowa, Ina-shi, Nagano,
399-4501 JAPAN

River Seiko Corporation Kohan Factory
2-6-16 Kohan, Okaya-shi, Nagano,
394-0034 JAPAN

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