ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTI

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 04 24736 060

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

EC-Representative:
KANEKA PHARMA EUROPE N.V.
Nijverheidsstraat 16
2260 Westerlo-Oevel
BELGIUM

Product Category(ies):
Suction Catheter Set, Catheter for Angioplasty and Balloon Dilation Catheter for Angioplasty

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: JNQ235029570

Valid from: 2017-08-17
Valid until: 2022-01-21

Date, 2017-08-17

Stefan Preiß

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 17:20:05 EET
Reason: Validation Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 04 24736 060

Facility(ies):

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 04 24736 065

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

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of Medical Device for Selective Plasma Component Adsorption, Medical Device for Blood Purification, Neuro Surgical Products, Catheters for Interventional Radiology, Surgical Products, Sillicone Tubing Ophthalmic Products, Cell Separation Device
Design and Development and Distribution of Plasma Separator, Blood Tubing Lines, Apheresis Unit
Distribution of Blood Flowmeter

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.: **JNQ235029570**

Valid from: **2017-09-01**
Valid until: **2020-08-31**

Date, 2017-08-17

Stefan Preiß

Page 1 of 2

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE
No. Q5 17 04 24736 065

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

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

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

KANEKA Medix Corporation Tokyo Logistics Center
1-4-3, Katsu-shima, Shinagawa-ku, Tokyo, 140-0012 JAPAN

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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 18 05 24736 068

Manufacturer:

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

EC-Representative:

KANEKA PHARMA EUROPE N.V.
Nijverheidsstraat 16
2260 Westerlo-Oevel
BELGIUM

Product: **Catheters for Single Use**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713121823

Valid from: 2018-06-19
Valid until: 2023-05-21

Date, 2018-06-19

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate
EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 18 05 24736 068

Model(s):

Dual Lumen Catheters
- Crusade Catheter KMF0114A
- FineDuo Catheter NC-D724

Parameters:

Effective length 1400 ± 20 mm
Maximum outer diameter 1.07 ± 0.02 mm
For guide wire size 0.014 inch (0.36 mm)
For guide catheter size 0.056 inch (1.44 mm)

Facility(ies):

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

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225-1, Aza Deguchi, Yamakita, Yamakita-machi,
Ashigara-Kami-gun, KANAGAWA, 258-0113 JAPAN

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Ward, Thuan An Town, Binh Duong Province, VIETNAM

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