ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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.

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 20:01:21 EET
Reason: MoldSign Signature
Location: Moldova

Report No.: **JNQ235029570**

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

Date, 2017-08-17

Stefan Preiß

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

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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

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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TÜV®

KANEKA
MEDICAL
PRODUCTS

DECLARATION OF CONFORMITY

1. Manufacturer:	**KANEKA Corporation** 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA 530-8288, JAPAN
2. European representative:	**KANEKA PHARMA EUROPE N.V.** Nijverheidsstraat 16, 2260 Westerlo-Oevel, BELGIUM
3. Product:	**Senri** **PTA balloon dilatation catheter**
4. Classification:	Class IIa, Rule 6 of annex IX of the MDD 93/42/EEC
5. Conformity assessment route:	Annex II excluding Section 4 of the MDD 93/42/EEC applied

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

6. Standard applied:	EN ISO 13485:2012/AC:2012, EN ISO 14971:2012, EN ISO 11135:2014, EN ISO 10555-1:2009
7. Notified body:	TÜV-SÜD Product Service GmbH (Identification No. 0123) Ridlerstrasse 65, D-80339 München, Germany
8. EC Certificate:	G1 17 04 24736 061

9. Start of CE-marking: LOT No. SP097283

10. Place, Date of Issue: Osaka, Japan (Place) 2017-09-19 (Date (yyyy-mm-dd))

11. Signature: K. Sanaka

Kazuaki Sanaka (QMS Management representative)