CERTIFICAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認證書 ◆ CERTIFICATE ◆ CERTIFIKAT

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 061

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):
Peripheral angioplasty balloon catheter

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: **2020-07-21**

Date, **2017-08-17**

Stefan Preiß

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

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

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(Devices in Class IIa, IIb or III)

No. G1 17 04 24736 061

Facility(ies):

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