



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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No. G7 18 05 24736 068**Model(s):****Dual Lumen Catheters****- Crusade Catheter KMF0114A****- FineDuo Catheter NC-D724****Parameters:**Effective length 1400 ± 20 mmMaximum 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

KANEKA Medix Corporation Kanagawa Plant

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

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