



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

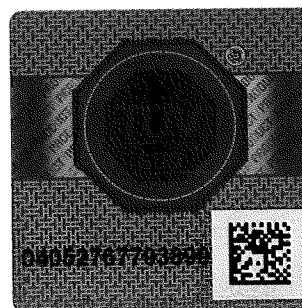
The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms 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.

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Valid from: 2017-08-17
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Date, 2017-08-17

Stefan Preiß



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

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No. G1 17 04 24736 061**Facility(ies):**

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

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Park, An Phu Ward, Thuan An Town, Binh Duong
Province, VIETNAM