



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 01 24736 056

**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

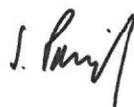
**Product Category(ies):** Suction Catheter Set, Catheter for Angioplasty and  
Balloon Dilation Catheter for Angioplasty

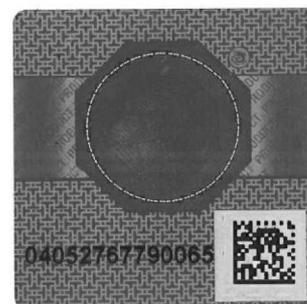
The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms 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.:** JNQ235025973

**Valid from:** 2017-01-22  
**Valid until:** 2022-01-21

**Date,** 2016-12-22

  
Stefan Preiß



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

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