

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 616532**
 Date: **2020-03-24**
 Issued To: **KANEKA Corporation**
3-18, 2-Chome, Nakanoshima
Kita-ku
Osaka-city, OSAKA
530-8288
Japan

Subcontractor:	Service(s) supplied
KANEKA Corporation Osaka Plant 5-1-1, Torikai-Nishi Settsu-city OSAKA 566-0072 Japan	Design Development
KANEKA Medix Corporation Kanagawa Plant 225-1, Aza Deguchi, Yamakita, Yamakita-machi, Ashigara-Kami-gun KANAGAWA 258-0113 Japan	ETO Sterilization Manufacture
KANEKA PHARMA EUROPE N.V. Nijverheidsstraat 16, 2260 Westerlo-Oevel, Belgium	EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
02 April 2015	8180614	First Issue
07 January 2016	8453305	Change of EU Authorized Representative address.
12 March 2019	8250566	Traceable to NB 0086.
Current	9757922	Certificate renewal. Word "sterile" added to scope and "related accessories" removed from scope. Addition of product table.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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