

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 09 01 60114 003

Manufacturer:

Saraya Co., Ltd.

2-2-8, Yuzato, Higashisumiyoshi-ku

Osaka-shi

Osaka

546-0013 JAPAN

EC-Representative:

Saraya Co., Ltd. Europe

Sint-Annadreef 68b

1020 Brussels

BELGIUM

Product

Disinfectants for Medical Devices

Category(ies):

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 products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

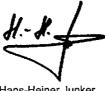
Report No.:

ONQ73520234A

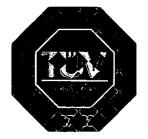
Valid until:

2014-02-04









TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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Facility(ies):

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