

# EC Certificate - Full Quality Assurance System

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

**No.****CE 716793**

## Issued To:

**Saraya Co., Ltd.  
2-2-8 Yuzato,  
Higashisumiyoshi-ku, Osaka-shi,  
Osaka  
546-0013  
Japan**

In respect of:

**Design, development and manufacture of disinfectants for endoscopic medical devices**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-05-07**Date: **2020-05-07**Expiry Date: **2024-05-26**

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Page 1 of 2

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

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## Supplementary Information to CE 716793

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**Saraya Co., Ltd.**  
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GMDN Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
45239	ACECIDE	Solution for high level disinfection of medical instruments (endoscopes)

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Page 2 of 2

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## List of Significant Subcontractors

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

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**Osaka**  
**546-0013**  
**Japan**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Saraya Co., Ltd. Biochemical Laboratory 24-12 Tamate-cho, Kashiwara-shi, Osaka 582-0028 Japan	<b>Design Development</b>
Saraya Co., Ltd. Iga Factory 1774-4 Yasogari, Yasuba, Iga-shi, Mie 518-1145 Japan	<b>Manufacture</b>
Saraya Co., Ltd. Europe Rue des Palais 44 1030 Brussels Belgium	<b>EU Representative</b>

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 716793**  
 Date: **2020-05-07**  
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Date	Reference Number	Action
Current	3066079	First issue.

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Page 1 of 1

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