By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 77715**

Issued To: **Fuji Systems Corporation**
Shirakawa Plant
200-2 Aza-Ohira,
Odakura, Nishigo,
Nishi Shirakawa Gun,
Fukushima
961-8061
Japan

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of Medical Drapes.

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

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

Albert Roossien, Regulatory Lead

First Issued: **2003-09-19** Date: **2019-02-26** Expiry Date: **2023-09-18**

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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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List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
Dr. Hans-Joachim Lau Flughafenstrasse 52a (Building C) 22335 Hamburg Germany	**EU Representative**
Fuji Systems Corporation Shin-Shirakawa Plant 1-23 Tsukinoiri Kayane Shirakawa Fukushima 961-0004 Japan	**Manufacture**
Radia Industry Co., Ltd 168 Ooyagi Takasaki Gunma 370-0072 Japan	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 77715**

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Date	Reference Number	Action
19 September 2003		First Issue.
22 May 2008	7202877	Addition of Sterile Medical Drapes. Addition of significant subcontractor Radia Industry. Removal of Sengensten-Blackmore tubing and Linton Naclas tubing from CE 77715 and transfer to CE 77043.
12 September 2008	7278860	Certificate renewal.
18 April 2011	7675397	Addition of KRAUTH Medical KG as EU representative and update to certificate address to include "Shirakawa Plant".
17 August 2012	7878110	Change of EU representative from KRAUTH Medical KG to Dr. Hans-Joachim Lau.
12 September 2013	8034545	Certificate renewal.
13 September 2018	9641024	Certificate renewal. Update to certificate scope to remove Self-Cath. Addition of subcontractor Fuji Systems Corporation Shin-Shirakawa Plant.
Current	7779309	Traceable to NB 0086.