By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 77043**

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

In respect of:

The design, development and manufacture of sterile intravascular occluding catheters and endotracheal tubing.

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):

Albert Roossien, Regulatory Lead

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

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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 77043**
Date:	**2019-02-26**
Issued To:	**Fuji Systems Corporation** **Shirakawa Plant** **200-2 Aza-Ohira,** **Odakura, Nishigo,** **Nishi Shirakawa Gun,** **Fukushima** **961-8061** **Japan**

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**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 77043**

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Date	Reference Number	Action
19 September 2003		First issue.
22 May 2008	7202874	Addition of Gastrostomy feeding balloon tube. Addition of Sengensten-Blackmore tubing and Linton Naclas tubing from CE 77715.
12 September 2008	7278861	Certificate renewal.
11 April 2011	7557229	Extension to scope to include Intravascular Catheters, addition of the EU Representatives details and update to manufacturers address to reference the Shirakawa Plant.
17 August 2012	7878109	Change of EU Representative from KRAUTH Medical KG to Dr. Hans-Joachim Lau.
12 September 2013	8034545	Certificate renewal.
13 September 2018	9640917	Certificate renewal. Update to certificate scope to remove nephrostomy catheters, urinary catheters, drainage catheters, tracheostomy tubing, gastrostomy feeding balloon tube, Sengstaken-Blakemore tubing and Linton Naclas tubing; sterile and non-sterile Trex gauze. Addition of subcontractor Fuji Systems Corporation Shin-Shirakawa Plant.
Current	7779309	Traceable to NB 0086.