

EC Certificate - Production Quality Assurance

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

No.**CE 77715**

Issued To:

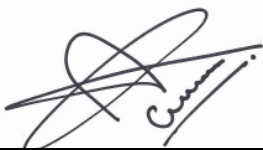
**Fuji Systems Corporation
Shirakawa Plant
200-2 Aza-Ohira,
Odakura, Nishigo,
Nishi Shirakawa Gun,
Fukushima
961-8061
Japan**

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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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.

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List of Significant Subcontractors

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

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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
Radia Industry Co., Ltd 168 Ooyagi Takasaki Gunma 370-0072 Japan	Gamma Sterilization

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EC Certificate - Production Quality Assurance Certificate History

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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.

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