By Royal Charter

EC Design-Examination Certificate

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

No. **CE 550009**

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

In respect of:

Intravascular Catheter with Cuff

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2011-04-11** Date: **2019-02-26** Expiry Date: **2021-04-10**

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EC Design-Examination Certificate

Supplementary Information to CE 550009

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200-2 Aza-Ohira,
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Japan

Product: Intravascular Catheter with Cuff

The following parameters apply to the family of products covered by this certificate:

Device Trade Name	Intravascular Occluding Catheter Variants				
	Catalogue Number(s)	Number of lumens	O.D. (mm)	Length Range (mm)	Size Range in French size (F)
CELLO	1610060, 1610070, 1610080, 1610090	2	2.00 -2.90	150 - 2000	6.0, 7.0, 8.0, 9.0

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Certificate History

Date	Reference Number	Action
11 April 2011	10117057	First issue.
17 September 2014	10151155	Change scope of certificate from "Intravascular Balloon Occlusion Catheters" to "Intravascular Catheter with Cuff" to align with the DOC and Labelling.
01 April 2016	10161193	Certificate Renewal. Removal of trade names and product codes for IC OCCLUDER, SPF CATHETER, MASAMUNE and IIGUMAN.
Current	7779309	Traceable to NB 0086.

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