By Royal Charter

EC Design-Examination Certificate

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

No. **CE 01495**

Issued To: **Codman & Shurtleff, Inc.**
325 Paramount Drive
Raynham
Massachusetts
02767-0350
USA

In respect of:

CODMAN® HAKIM® Programmable Valve System and Accessories including Micro Programmable Valve System

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **07 January 1997** Date: **16 December 2016** Expiry Date: **06 January 2022**

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Programmable Valve System:

Family	Catalogue No
With Pre-chamber	82-3100
Without Pre-chamber	82-3101
In-Line with Reservoir, SiphonGuard and Integral Connector	82-3832
In-Line, with Reservoir and Integral Connector	82-3834
Right Angle, with Reservoir and SiphonGuard	82-3136
Right Angle, with Reservoir and Integral Connector	82-3838

Micro Programmable Values

Family	Catalogue No
Codman Hakim Micro Programmable Valve and Integral Reservoir	82-3113
Codman Hakim Micro Programmable Valve System	82-3114

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Programmable Unitized Valve Systems:

Family	Catalogue No
With Pre-Chamber	82-3111
In-Line, with Reservoir, SiphonGuard and Integral Connector	82-3842
In-Line, with Reservoir and Integral Connector	82-3844
Right Angle, with Reservoir and SiphonGuard	82-3146
Right Angle, with Reservoir	82-3148

Catheter-Silicone Elastomer-Radiopaque:

Family	Catalogue No
Straight ventricular catheter with style and right angle adaptors	82-3041
Atrial drainage catheter	82-3044

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Certificate History

Date	Reference Number	Action
7 January 1997	MD000175	First Issue.
17 January 2000	MD000636	Addition of Catalogue Nos.
16 October 2000	EQ 10018279	Addition of Catalogue No and change of Company Address
21 May 2002	EQ 10039301 EQ 10033310	Addition of Catalogue Nos. 5 Year renewal.
20 December 2002	EQ 10044256	Correction of 'Radiopague' to read 'Radiopaque'.
16 December 2003	EQ 10054182	Change of sterilization process to Sterigenics Belgium.
15 September 2004	EQ 10061347 & EQ 10061518	Addition of Sterigenics, France and addition of an alternative epoxy resin for use in the manufacture of the product
7 March 2005	EQ 10065210	Addition of Barium Catheters
5 December 2005	EQ 10073677	Change of IFU to allow use up to 3 Tesla MRI exposures
09 March 2006	EQ 10078093	Transfer of catalogue numbers 82-3112, 82-3113 and 82-3114 from CE 01239 to CE 01495
29 January 2007	EQ 10082971	Renewal of certificate
28 March 2007	EQ 10083600	Modification to the CHPV silicone housing used with Siphon Guard

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Date	Reference Number	Action
25 January 2012	EQ 10132382	Certificate Renewal Removal of 17 Catalogue Numbers from the Certificate
26 January 2016	10158753	Change affecting Tyvek 1073®B packaging materials – all product codes are affected.
24 June 2016	10158378	Added ethylene oxide sterilization chamber, chamber #4, and modified sterilization protocol in chamber #3 to align with the protocol in chamber #4, for contract sterilizer Sterigenics Belgium (Petit Rechain)
16 December 2016	10166357	Certificate Renewal.

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