By Royal Charter

EC Design-Examination Certificate

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

No. **CE 01239**

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

In respect of:

CODMAN® HAKIM® Precision Valve Systems including Micro Precision Valve Systems

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: **06 March 1996** Date: **24 June 2016** Expiry Date: **05 March 2021**

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PRODUCT: CODMAN® HAKIM® Precision Valve Systems including Micro Precision Valve Systems

a) Standard

Family	**Catalogue No**
With Pre-chamber	82-3001 – 82-3005
In-Line with Reservoir and Integral Connector	82-3816 – 82-3820
In-Line with Reservoir, SiphonGuard and Integral Connector	82-3811 – 82-3815
Right Angle with Reservoir and Integral Connector	82-3801 – 82-3805
Right Angle with Reservoir and SiphonGuard	82-3361 – 82-3365

b) Paediatric (without pre-chamber)

Family	**Catalogue No**
	82-3016 – 82-3020

c) Unitized (attached distal catheter)

Family	**Catalogue No**
Pre-Chamber	82-3006 – 82-3010
In-Line with Reservoir and Integral Connector	82-3806 – 82-3810
In-Line with Reservoir, SiphonGuard and Integral Connector	82-3821 – 82-3825
In-Line with Reservoir and Unitized Ventricular Catheter	NS5123
Right Angle with Reservoir	82-3281 – 82-3285
Right Angle with Reservoir and SiphonGuard	82-3261 – 82-3265

d)

Family	**Catalogue No**
Codman Hakim Micro Precision Valve & Integral Reservoir	82-3021 – 82-3025

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PRODUCT: CODMAN® HAKIM® PRECISION VALVE SYSTEMS INCLUDING MICRO PRECISION VALVE SYSTEMS

e)

Family	Catalogue No
Codman Hakim Micro Precision Valve Systems	82-3035 – 82-3039
Codman Hakim Micro Precision Valve Systems with Unitized Ventricular Catheter	NS5117, NS5118

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Date	Reference Number	Action
6 March 1996	MD000091	First Issue
2 October 1997	MD000263	Extension to Scope and addition of Catalogue Nos.
20 January 2000	MD000636	Extension to Scope
16 October 2000	EQ 10018279	Change to Company Name & Address and addition of Catalogue Nos.
23 November 2001	EQ 10023111	5 year renewal
21 May 2002	EQ 10039301	Addition of Catalogue Nos.
20 December 2002	EQ 10044256	Certificate Re-issue
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.
5 December 2005	EQ10073677	Change of IFU to allow use up to 3 Tesla MRI exposures
09 March 2006	EQ 10078093	Certificate renewal Transfer of catalogue numbers 82-3112, 82-3113 and 82-3114 to CE 01495
28 March 2007	EQ 10083600	Modification to the CHPV silicone housing used with Siphon Guard

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Date	Reference Number	Action
27 April 2007	EQ 10087723	Addition of catalogue numbers NS5121-NS5125 and NS5116-NS5120
29 July 2009	EQ 10102199	Packaging changes - New blister tray and lid. Change of coating material for Tyvek blister pack lid for Catalogue No. 82-1520.
24 May 2011	10123040	Remove product codes - 82-3341-823345, 82-3321-82-3325, 82-3381-82-3385, 0068CSD, 0069CSD, 82-3241 – 82-3245, 82-3221 – 82-3225, 0041CSD, 0042CSD, 82-3011 - 82-3015, 82-3026 – 82-3030, 82-1504, 82-1507, 82-1520, 82-8591, 82-1515, 82-1516. Replace NS5121-NS5125 with NS5123 and NS5116-NS5120 with NS5117, NS5118. Certificate renewal.
26 January 2016	10158753	Change affecting Tyvek 1073®B packaging materials – all product codes are affected.
29 February 2016	10160075	Certificate Renewal and removal of product code 82-3041

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Date	Reference Number	Action
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)

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