By Royal Charter

EC Design-Examination Certificate

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

No. **CE 01584**

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

In respect of:

CODMAN® Microsensor Basic Kit, Ventricular Catheter Kit, Skull Bolt Kit, Double Lumen Skull Bolt Kit and Accessory Kit

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: **24 April 1997** Date: **24 June 2016** Expiry Date: **23 April 2017**

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Supplementary Information to CE 01584

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Product

Description	Catalogue No.
Codman MicroSensor Basic Kit	Model 82-6631
Codman MicroSensor Skull Bolt Kit	Model 82-6632, 82-6638, 82-6639
Codman MicroSensor Ventricular Catheter Kit	Model 82-6633, 82-6653
Codman Single Lumen Skull Bolt Kit	Model NS9011
Codman Double Lumen Skull Bolt Kit	Model 82-6724
Touhy-Borst Adaptor and Male Luer Cap Accessory Kit	Model 82-6730
Microsensor Basic Kit	Model 62-6631
Microsensor Plastic Skull Bolt Kit	Model 62-6632
Microsensor Ventricular Catheter Kit with Tuohy-Borst Adapter	Model 62-6633
Microsensor Metal Skull Bolt Kit	Model 62-6638
Microsensor Ventricular Catheter Kit	Model 62-6653

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Certificate History

Date	Reference Number	Action
24 April 1997	MD000043	Initial issue
27 April 1998	MD000369	Component variations
01 November 2000	EQ 10017504	Amendment
28 June 2002	EQ 10039904	5 yearly renewal
07 May 2003	EQ 10049178	Material amendment
16 December 2003	EQ 10054182	Change of sterilization process to Sterigenics Belgium
07 April 2005	EQ 10061347	Review of design dossier amendment to include Sterigenics, Anse as an additional sub contractor
04 August 2005	EQ 10068873	The IFU's for the products have been changed
05 December 2005	EQ 10073146	Further changes to the IFU, MRI Addendum sheet for clarity
29 May 2007	EQ 10088354	Renewal of certificate
26 March 2008	EQ 10095831	Addition of Single Lumen Skull Bolt Kit, Product Code: NS9011
29 January 2009	EQ 10099056	Addition of Double Lumen Skull Bolt Kit, Model 82-6724 and Touhy-Borst Adaptor and Male Luer Cap Accessory Kit, Model 82-6730
31 May 2012	EQ 10135367	Renewal of certificate

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Date	Reference Number	Action
27 August 2015	10153182	Add 62-6631, 62-6632, 62-6633, 62-6638, and 62-6653 with updated materials for compliance with RoHS 2011/65/EU and MR Conditional labelling with 1.5T MRI scanners. Indications in IFUs for new microsensor kits includes a statement that sensor performance has been evaluated for a maximum monitoring period of 30 days.
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)

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