

EC Design-Examination Certificate

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

No.**CE 01584****Issued To:**

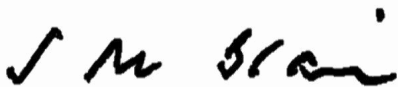
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham
Massachusetts
02767-0350
USA

In respect of:

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **24 April 1997**

Date: **21 April 2017**

Expiry Date: **23 April 2022**

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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 certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 01584

Issued To:

Codman & Shurtleff, Inc.
325 Paramount Drive
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Product

Description	Catalogue No.
Codman Single Lumen Skull Bolt Kit	Model NS9011
Codman Double Lumen Skull Bolt Kit	Model 82-6724
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)
06 April 2017	10160042	Extend 62-6631, 62-6632, 62-6633, 62-6638, and 62-6653 MR Conditional labeling to include 3T MRI scanners. Removal of maximum monitoring period of 30 days in indications in IFUs, with zero drift specification still included.

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Certificate History

Date	Reference Number	Action
21 April 2017	10168748	Renewal of Certificate and removal of non-RoHS product codes: 82-6730 (Accessory kit), 82-6631, 82-6632, 82-6638, 82-6639, 82-6633, 82-6653.

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.