

EC Design-Examination Certificate

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

No.**CE 02289****Issued To:**

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

In respect of:

CODMAN* Lumbar Drainage Catheter Kits II

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 April 1999**

Date: **26 January 2016**

Expiry Date: **06 April 2019**

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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

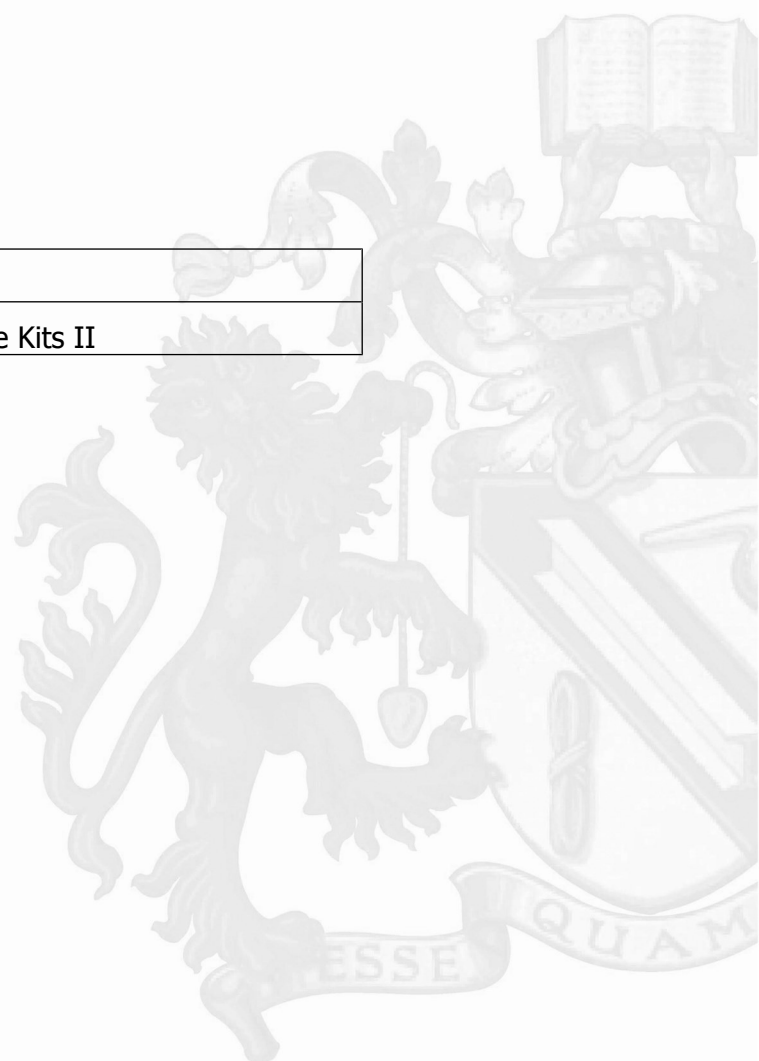
Supplementary Information to CE 02289

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Product: CODMAN* Lumbar Drainage Catheter Kits II

Cat. Nos.	Product
82-1707	Lumbar Drainage Kits II



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 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.

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Certificate History

Date	Reference Number	Action
07 April 1999	MD 000363	First Issued
19 August 2004	10061378	5 year certificate renewal and company name and address changed.
18 July 2007	10088384	Change to guidewire from teflon coated to hydrophilic coated and reduced overall dimensions. Change of packaging configuration and IFU.
21 August 2009	10105715	Certificate renewal
01 April 2014	10145701	Certificate renewal. Removal of product codes 82-1708 and 82-1709.
26 January 2016	10158753	Change affecting Tyvek 1073®B packaging materials – all product codes are affected.

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