By Royal Charter

EC Design-Examination Certificate

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

No. **CE 01068**

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

In respect of:

CODMAN® External Drainage Systems. CODMAN® Bactiseal External Ventricular Drainage Catheter Sets. CODMAN® EDS3™ CSF External Drainage System with and without Ventricular Catheter. CODMAN® EDS3™ Clear Ventricular CSF Catheter 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: **1995-12-08** Date: **2017-06-07** Expiry Date: **2020-12-07**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01068

Issued To:

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

Product:

Catalogue Nos.	Family Name
82-1705	CODMAN® External Drainage Ventricular Catheter Set
82-1706	CODMAN® Lumbar External Drainage Set
82-1745	CODMAN® BACTISEAL™ EVD Catheter Set (1 pack)
82-1749	CODMAN® BACTISEAL™ EVD Large Lumen Catheter Set
82-1730	CODMAN® EDS3™ CSF External Drainage System with Ventricular Catheter
82-1735	CODMAN® Clear Ventricular CSF Catheter Kit
82-1739	CODMAN® Clear Large Lumen Ventricular CSF Catheter Kit
82-1750	CODMAN® BACTISEAL™ Clear EVD Catheter Set

First Issued: **1995-12-08** Date: **2017-06-07** Expiry Date: **2020-12-07**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01068

Issued To:

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

Certificate History

Date	Reference Number	Action
08 December 1995	MD 000068	First Issue
14 November 2000	EQ 1001 7310	Scope amendment
08 December 2000	EQ 1002 0708	5 Yearly renewal
07 May 2003	EQ 1004 9178	Material amendment
12 June 2003	EQ 1004 9123	Scope amendment to include EVD system coated with BACTISEAL Silicone
16 December 2003	EQ 1005 3351 EQ 1005 4182	Codman EDS3 ™ CSF External Drainage systems and Ventricular Catheter added to the product listings. Change of sterilization process to Sterigenics, Belgium
22 June 2004	EQ 1005 6530	The sterilization method used with product code 82-1735 has been amended
14 October 2004	EQ 1006 1347	Addition of Sterigenics, France

First Issued: **1995-12-08** Date: **2017-06-07** Expiry Date: **2020-12-07**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01068

Issued To:

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

Certificate History

Date	Reference Number	Action
21 December 2004	EQ 1006 3076	Change to the packaging and method of sterilization for the CODMAN® BACTISEAL™ EVD Catheter Sets. (product codes 82-1745 and 82-1746) A Catheter anchoring clip added to the CODMAN® BACTISEAL™ EVD Catheter Set (product code 82-6653 deriving from certificate CE 01584)
02 December 2005	EQ 1007 3884	Certificate renewal
07 February 2006	EQ 1007 7487	Additional caution statements added to the IFU's for the EDS II and EDS 3 systems
07 April 2006	EQ 10078697	A change in the method of sterilization validation
18 October 2006	EQ 10081710	Approval of Parametric Release for Bactiseal Catheters. Wild Cards in Catalogue Numbers removed. "Accessories" removed from the product listing
30 November 2006	10082165	Addition of caution and warning statements to the IFU's for the EDS 3 External Drainage System.
06 July 2007	10081333	Addition of model numbers 82-1739 and 82-1749
18 December 2008	10097021	Change of supplier of Clindamycin HCI from Pharmacia and Upjohn (now merged with Pfizer to ACS Dobfar SpA)

First Issued: **1995-12-08** Date: **2017-06-07** Expiry Date: **2020-12-07**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01068

Issued To:

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

Certificate History

Date	Reference Number	Action
24 March 2009	10103333	Addition of CODMAN® BACTISEAL™ Clear EVD Catheter Set
29 July 2009	10102199	Change of packaging configuration for Catalogue No. 82-1706 to a new blister tray in a pouch folded on the chevron side, in a unit box.
20 March 2010	10102323	Changes to the EDS3 burette cap
23 May 2011	EQ 10119517	Certificate renewal. Removal of product codes 82-1700 CODMAN® External Drainage System, 82-1731 CODMAN® EDS3™ CSF External Drainage System without Ventricular Catheter and 82-1746 CODMAN® BACTISEAL™ EVD Catheter Set (5 pack)
22 August 2012	EQ 10136858	Change to Clindamycin HCL manufacturing process for devices containing Bactiseal.
04 December 2015	10158579	Certificate renewal. Removal of product code 82-1720 CODMAN® External Drainage Systems II.

First Issued: **1995-12-08** Date: **2017-06-07** Expiry Date: **2020-12-07**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01068

Issued To:

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

Certificate History

Date	Reference Number	Action
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)
07 June 2017	10166352	Transfer of manufacturing activities to Medos SARL, Rue Girardet 29, Le Locle, CH-2400, Switzerland for device 82-1730. Change of bonding agent to Loctite 3294 for device 82-1730. Clarification of Indications For Use for External Drainage Systems.

First Issued: **1995-12-08** Date: **2017-06-07** Expiry Date: **2020-12-07**

...making excellence a habit.™