

EC Design-Examination Certificate

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

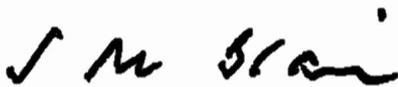
No. **CE 01886**
Issued To: **Codman and Shurtleff, Inc.**
325 Paramount Drive
Raynham
Massachusetts
02767-0350
USA

In respect of:

Codman® Shunt Products with BACTISEAL Silicone

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: **1998-04-27**

Date: **2018-04-23**

Expiry Date: **2023-04-26**

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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 01886

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Product Code	Product Description
82-3072	Ventricular Catheter and Peritoneal Catheter Set with Bactiseal
82-3073	Ventricular Catheter with Bactiseal, 14cm
82-3074	Peritoneal Catheter with Bactiseal, 120 cm
82-8551	Bactiseal Universal Shunt – Low Pressure
82-8552	Bactiseal Universal Shunt – Medium Pressure
82-8553	Bactiseal Universal Shunt – High Pressure

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Certificate History

Date	Reference Number	Action
27 April 1998	MD 000248	First issue
21 May 2003	EQ 10049175	Catheter Length increase
11 June 2003	EQ 10050888	Five yearly renewal
16 December 2003	EQ 10054182	Change of sterilization process to Sterigenics, Belgium.
7 April 2005	EQ 10061347	Change of company name. Review of design dossier amendment to include Sterigenics, Anse as an additional sterilization sub contractor
5 December 2005	EQ 10073677	Change of IFU to allow use up to 3 Tesla MRI exposures
18 October 2006	EQ 10081710	Parametric release approval for Bactiseal Catheters Change to the IFU
26 June 2008	EQ 10098354	Certificate renewal
18 December 2008	EQ 10097021	Change of supplier of Clindamycin HCl from Pharmacia and Upjohn (now merged with Pfizer to ACS Dobfar SpA)

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Date	Reference Number	Action
24 March 2009	EQ 10103129	Addition of Bactiseal Universal Shunt Product Codes 82-8551, 82-8552, 82-8553
12 September 2011	EQ 10130154	Removal of HAKIM branding from peritoneal and ventricular catheter product codes 82-3072, 82-3073, 82-3074
22 August 2012	EQ 10136858	Change to Clindamycin HCL manufacturing process for devices containing Bactiseal.
16 April 2013	EQ 10140396	Certificate Renewal. Removal of class IIb devices.
26 January 2016	10158753	Change affecting Tyvek 1073®B packaging materials – all product codes are affected.
Current	8860525	Certificate Renewal.

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