

# EC Design-Examination Certificate

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

**No.** **CE 01069**  
Issued To: **Codman & Shurtleff, Inc.**  
**325 Paramount Drive**  
**Raynham**  
**Massachusetts**  
**02767-0350**  
**USA**

In respect of:

**Codman<sup>®</sup> Holter Products**

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: **08 December 1995**

Date: **04 December 2015**

Expiry Date: **07 December 2020**

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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 01069

Issued To:

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### Product:

Catalogue No.	Family Name
82-1630	Ventricular Catheter – Reservoir, 3 cm
82-1632	Ventricular Catheter – Reservoir, 4 cm
82-1634	Ventricular Catheter – Reservoir, 5 cm
82-1636	Ventricular Catheter – Reservoir, 6 cm
82-1638	Ventricular Catheter – Reservoir, 7 cm
82-1640	Ventricular Catheter – Reservoir, 8 cm
82-1642	Ventricular Catheter – Reservoir, 9 cm
82-1644	Ventricular Catheter – Reservoir, 10 cm
82-1650	Ventricular Right Angle Catheter, 15 cm
82-1652	Ventricular Right Angle Catheter, 3 cm
82-1654	Ventricular Right Angle Catheter, 4 cm
82-1656	Ventricular Right Angle Catheter, 5 cm
82-1658	Ventricular Right Angle Catheter, 6 cm
82-1660	Ventricular Right Angle Catheter, 7 cm
82-1662	Ventricular Right Angle Catheter, 8 cm

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### Product:

Catalogue No.	Family Name
82-1664	Ventricular Right Angle Catheter, 9 cm
82-1666	Ventricular Right Angle Catheter, 10 cm
82-1670	Holter Distal Atrial Catheter, Type A, Barium, 45 cm
82-1672	Holter Distal Atrial Catheter, Type B, Barium Two Piece, Total Length 38 cm
82-1674	Holter Distal Atrial Catheter, Type C, Barium, Total Length 42 cm
82-1676	Holter Distal Atrial Catheter, Type E, Barium, Total Length 48 cm
82-1678	Holter Distal Atrial Catheter, Type H, Barium; Total Length 41 cm

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## Certificate History

Date	Reference Number	Action
08 December 1995	MD 000042	First Issue
08 December 2000	EQ 1002 0708	Certificate renewal
02 December 2005	EQ 1007 3884	Certificate renewal
29 July 2009	EQ 10102199	Change of packaging configuration to a new sealed blister tray, lid and pouch, in a unit box for catalogue numbers 82-1630,82-1632,82-1634,82-1636,82-1638,82-1640,82- 642,82-1644,82-1650,82-1652,82-1654,82-1656,82-1658, 82-1660, 82-1662, 82-1664, 82-1666. New blister tray, lid and pouch and change of coating material for Tyvek blister pack lid for Catalogue Nos. 82-1684. 82-1670, 82-1672, 82-1674 82-1676 82-1678,82-1682.
24 May 2011	EQ 10119526	Certificate renewal. Removal of peritoneal catheters and accessories (Class IIb devices previously misclassified as Class III).
22 June 2011	EQ 10122608	Addendum for MRI compatibility

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## Certificate History

Date	Reference Number	Action
04 December 2015	10158712	Certificate renewal.

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