

EC Design-Examination Certificate

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

No. CE 01070
Issued To: **Codman & Shurtleff, Inc.**
325 Paramount Drive
Raynham
Massachusetts
02767-0350
USA

In respect of:

Codman® Accu-Flo 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**

...making excellence a habit.™

Page 1 of 4

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 01070

Issued To:

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

Product:

| Catalogue Nos. | Family Name |
|----------------|---------------------------------|
| 82-1201 | Accuflo Vent Catheter |
| 82-1203 | Accuflo Clear Vent Catheter |
| 82-1221 | Accuflo Dotted Vent Catheter |
| 82-1231 | Accuflo Barium RA Vent Catheter |
| 82-1232 | Accuflo Barium RA Vent Catheter |
| 82-1233 | Accuflo Barium RA Vent Catheter |
| 82-1234 | Accuflo Barium RA Vent Catheter |

First Issued: **08 December 1995**

Date: **04 December 2015**

Expiry Date: **07 December 2020**

...making excellence a habit.™

Page 2 of 4

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 01070

Issued To:

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

Certificate History

| Date | Reference Number | Action |
|------------------|------------------|--|
| 8 December 1995 | MD000071 | First Issue. |
| 8 December 2000 | EQ 10020708 | 5 year renewal. |
| 16 December 2003 | EQ 1005 4182 | New Format. Change of sterilization process to Sterigenics, Belgium |
| 7 April 2005 | EQ 10061347 | Review of design dossier amendment to include Sterigenics, Anse as an additional sub contractor |
| 2 December 2005 | EQ 1007 3884 | Certificate Renewal |
| 29 July 2009 | EQ 10102199 | Change of packaging configuration to a new sealed blister tray in a new pouch, in a unit box for Catalogue Nos. 82-1201, 82-1221, 82-1231, 82-1232, 82-1233, 82-1234, 82-1421. New blister tray and lid in a new pouch for Catalogue Nos. 82-1301, 82-1302, 82-1203, 82-1380. Change of packaging configuration to a new blister tray and lid in a new pouch and a separate blister tray. Change of coating material for Tyvek blister pack lid for Catalogue Nos. 82-6100, 82-6101. |

First Issued: **08 December 1995**

Date: **04 December 2015**

Expiry Date: **07 December 2020**

...making excellence a habit.™

Page 3 of 4

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 01070

Issued To:

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

Certificate History

| Date | Reference Number | Action |
|------------------|------------------|---|
| 24 May 2011 | EQ 10119527 | Certificate Renewal. Removal of product codes 82-13XX (Distal slit valve catheters), 82-13XX (Accu-Flo Catheters, Clear) 82-14XX (Accu-Flo Pressure Valves) and 82-61XX (Accu-Flo Reservoirs). As the number of catalogue items covered by this certificate is now much reduced, the wildcard format is no longer required, and products codes have been re-formatted |
| 04 December 2015 | 10158580 | Certificate renewal. |

First Issued: **08 December 1995**

Date: **04 December 2015**

Expiry Date: **07 December 2020**

...making excellence a habit.™