By Royal Charter

EC Design-Examination Certificate

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

No. **CE 561259**

Issued To: **Merit Medical Systems, Inc.**
1600 West Merit Parkway
South Jordan
Utah
84095
USA

In respect of:

Merit Embolectomy Catheters

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):

Digitally signed by Cucerenco Olesea
Date: 2019.09.17 12:15:27 EEST
Reason: MoldSign Signature
Location: Moldova

Frank Lee, EMEA Compliance & Risk Director

First Issued: **07 July 2010** Date: **11 March 2016** Expiry Date: **06 July 2020**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 561259

Issued To:

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan
Utah
84095
USA

Merit Embolectomy Catheter Catalogue Number:

- ASAP100
- ASAPLP

First Issued: **07 July 2010** Date: **11 March 2016** Expiry Date: **06 July 2020**

...making excellence a habit.™

bsi.

By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 561259

Issued To:

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan
Utah
84095
USA

Certificate History

Date	Reference Number	Action
07 July 2010	10116015	First Issue
07 July 2010	10116686	Addition of alternative sterilization cycles at Sterigenics, Salt Lake City and Caridian BCT, Colorado.
07 February 2012	10132674	Addition of manufacturing location for ASAP Catheter subassembly at Merit South Jordan, Utah facility.
16 January 2013	10137962	Changes to the packaging tray and pouch, introduction of DEHP-Free tubing within the Tubing Set and a supplier change for the ink used to print the catheter hub.
30 August 2013	10143247	Addition of ASAPLP Low Profile Aspiration Catheter Kit.
01 July 2015	10155151	Certificate Renewal and review of extension to shelf life
11 March 2016	10159617	Change affecting Tyvek® 1073B and Tyvek® 1059B packaging materials - All product codes are affected.

First Issued: **07 July 2010** Date: **11 March 2016** Expiry Date: **06 July 2020**

...making excellence a habit.™