By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 673136**

Issued To: **Merit Medical Singapore Pte. Ltd.**
198, Yishun Avenue 7
768926
Singapore

In respect of:

The design, development and manufacture of sterile, disposable blood pressure transducers and monitoring devices, kits and associated pressure monitoring and fluid administration accessories, supportive insertion and post-operation management components, coronary and peripheral catheters, cannulae, central venous catheters and introducers.
Those aspects of Annex II related to metrology in the manufacture of reusable pressure transducers.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-05-16** Date: **2020-10-01** Expiry Date: **2023-06-09**

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Supplementary Information to CE 673136

Issued To:

Merit Medical Singapore Pte. Ltd.
198, Yishun Avenue 7
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Number	Device Name	Intended purpose per IFU
Class III		
MD 0106, MDS 7006	Exacta™ Percutaneous Sheath Introducer Kits	See CE 672995
MD 0102, MDS 7006	Careflow™ Central Venous Catheter and Catheterization Kits	See CE 672996
MD 0102, MDS 7006	Secalon™ Seldy/Secalon™ T Central Venous Catheters	See CE 672998
MD 0102, MDS 7006	Criticath™ Pulmonary Artery Catheters for Pressure Monitoring and Thermodilution	See CE 672999
MD 0102, MDS 7001, MDS 7006	Hydrocath™ Assure Central Venous Catheter Kits	See CE 673000
Class IIa		
MD 0102, MDS 7006	Peripheral Arterial Catheters	---
MD 0106, MDS 7006	Peripheral Arterial Catheters, Cannulae	---
MD 1101, MD 0102, MD 0104, MDS 7006	Disposable Blood Pressure Transducers and Monitoring Devices, Kits	---

First Issued: **2017-05-16** Date: **2020-10-01** Expiry Date: **2023-06-09**

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102, MDS 7006	Pressure Monitoring Accessories and Fluid Administration Accessories	---
MD 0102, MDS 7006	Supportive insertion and post-operation management components	---
Class Im		
MD 0104 (non-sterile)	Reusable Pressure Transducer	---

First Issued: **2017-05-16** Date: **2020-10-01** Expiry Date: **2023-06-09**

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 673136**
Date:	**2020-10-01**
Issued To:	**Merit Medical Singapore Pte. Ltd.** **198, Yishun Avenue 7** **768926** **Singapore**

Subcontractor:	**Service(s) supplied**
ACME Monaco Asia Pte. Ltd. 1 Genting Link, #04-05/06 Perfect One, 349518 Singapore	**Manufacture**
Carlisle Medical Technologies (Dongguan) Co., Ltd No. 2, Xinhu Industrial Park, Qiaolong Road, Dengwu Village, Qiaotou Town Dongguan 523533 Guangdong China	**Manufacture**
Merit Medical Ireland Ltd. Parkmore Business Park West Galway Ireland	**EU Representative** **Manufacture**

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Certificate No:	**CE 673136**
Date:	**2020-10-01**
Issued To:	**Merit Medical Singapore Pte. Ltd.** **198, Yishun Avenue 7** **768926** **Singapore**

Subcontractor:	**Service(s) supplied**
Parker Hannifin CSS Merrillville 1201 East 86th Place Merrillville Indiana 46410 USA	**Manufacture**
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers, Liege B-4800 Belgium	**ETO Sterilization**
Sterile Services (Singapore) Pte. Ltd. No. 47 Jalan Buroh, Unit #01-01, Singapore 619491	**ETO Sterilization**

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Certificate No:	**CE 673136**
Date:	**2020-10-01**
Issued To:	**Merit Medical Singapore Pte. Ltd.** **198, Yishun Avenue 7** **768926** **Singapore**

Subcontractor:	**Service(s) supplied**
TE Connectivity Medical Maquilas Teta Kawi S.A de C.V, Carr. Int. KM 1969, Guadalajara-Nogales, Empalme, Sonora 85340 Mexico	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 673136**
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Date	Reference Number	Action
16 May 2017	8730309	First Issue. Mirror certificate to CE 01982.
08 June 2018	8934926	Certificate renewal. Subcontractors address change: The Parker Hannifin location has been changed from the Ventura, CA facility to the Merriville, IN facility. (Class Im device) LHI Technology has been removed as a significant subcontractor. Carlisle Medical Technologies (Dongguan) Co. Ltd has been added. (Class Im device)
08 August 2018	9627423	Addition of subcontractor: Sterile Services (Singapore) at No. 47 Jalan Buroh.
07 March 2019	9750626	Traceable to NB 0086.
17 October 2019	3069155	Removal of subcontractor Sterile Services (Singapore) CWT Distripark. Correction of subcontractor names/addresses for Carlisle Medical Technologies (Dongguan) Co., Ltd, TE Connectivity Medical, and Parker Hannifin CSS Merrillville. Addition of device table.
28 February 2020	9768839	Addition of sterilization subcontractor Sterigenics Belgium (Petit-Rechain).
Current	3271324	Added "Manufacture" to the services supplied by Merit Medical Ireland Ltd. Correction of address to state Singapore once.