



By Royal Charter

# EC Certificate - Full Quality Assurance System

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

**No.** CE 541900  
Issued To: **Merit Medical Systems, Inc.**  
**1600 West Merit Parkway**  
**South Jordan**  
**Utah**  
**84095**  
**USA**

In respect of:

**See certificate scope page.**

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 0086):

Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2008-10-03**

Date: **2018-10-01**

Expiry Date: **2023-10-02**

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Page 1 of 2

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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 541900

## Certificate Scope:

**The design, development and manufacture of sterile angiographic, angioplasty and other procedure kits/packs, angiographic catheters, cardiac catheters, vascular catheters, peripheral catheters, guiding catheters, guide wires (coated and uncoated), vascular trocars, introducer needles, angiographic needles, hemodialysis catheters, introducer devices, dilators, transducers, drainage devices, contrast management devices, embolectomy devices, snare devices, hemostasis devices, balloon inflation systems, scalpels, tubing, manifolds/stopcocks, valves, syringes, tracheobronchial stent systems, esophageal stent systems, biliary stent systems, stent positioning system intended for coronary or renal interventional procedures, Peritoneal Dialysis Catheters, accessories and kits, embolization particles, biopsy instruments and accessories, vascular grafts, graft accessory component kits, orthopedic bone cement, bone cement delivery devices/accessories, orthopedic surgical instruments and RF tumor ablation systems for orthopedic applications, percutaneous transluminal angioplasty (PTA) catheters, caps for the disinfection of vascular access connectors.**

**Those aspects of Annex II related to securing and maintaining sterility in the manufacture of angiographic, angioplasty and other procedure kits/packs, anesthesia conduction catheter fixation devices, catheter flush devices, infusion systems, syringes, suture retention devices, torque devices, drainage/waste/sharps collection devices, surgical/general purpose organizers, abdominal binders, labeling sets, compression devices, balloon inflation systems, non-vascular balloon catheter systems and all related accessories.**

**Those aspects of Annex II related to metrology in the manufacture of syringes, pressure monitors, tracheal measuring devices, balloon inflation systems and all related accessories.**

First Issued: **2008-10-03**

Date: **2018-10-01**

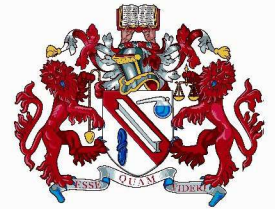
Expiry Date: **2023-10-02**

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Page 2 of 2

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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No:

**FM 534441**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2008-09-05

Latest Revision Date: 2018-12-20

Effective Date: 2017-12-21

Expiry Date: 2020-12-20

Page: 1 of 4

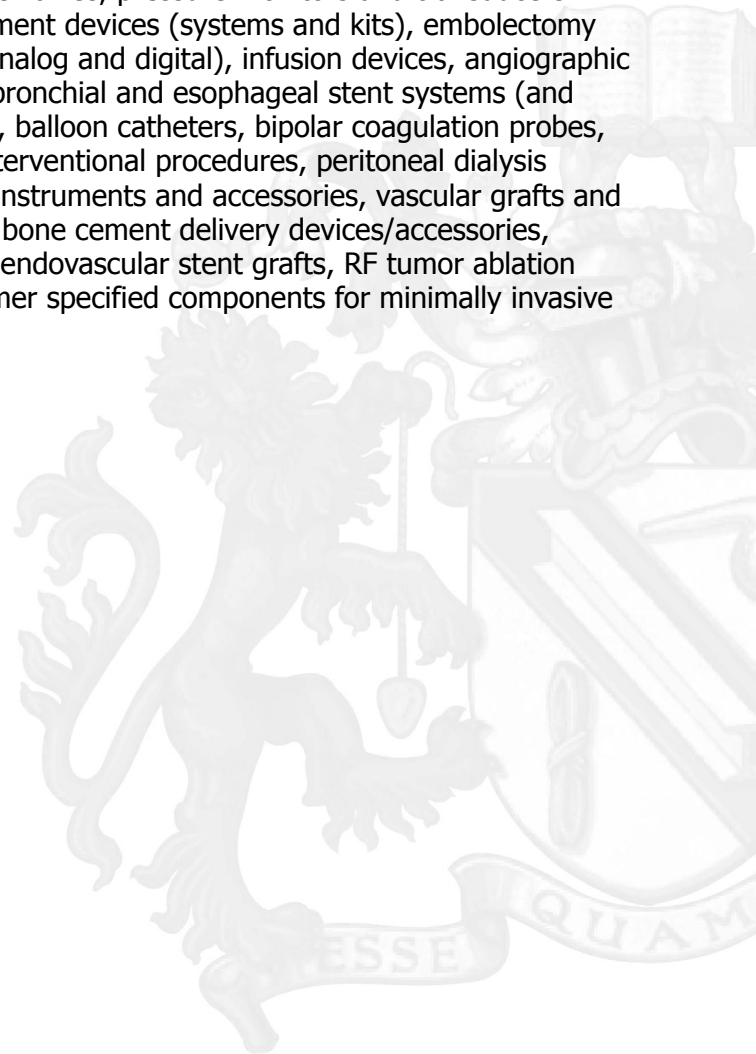


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Certificate No: **FM 534441**

## Registered Scope:

The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) including angiographic, angioplasty and other procedure kits/packs, angiographic catheters, vascular catheters, peripheral catheters, guiding catheters, guidewires (coated and uncoated), occluding guidewires, guidewire insertion tools, introducer needles, trocars, hemodialysis catheters, obturators, sharps holders, kits, introducer devices, insertion devices, torque devices, waste disposal systems, flush devices, fluid administration/handling devices (including high and low pressure – tubing, manifolds, stopcocks, valves) and kits, dilators, hemostasis valves, pressure monitors and transducers (including electronic), drainage devices, contrast management devices (systems and kits), embolectomy devices, snare devices and accessories, inflation device (analog and digital), infusion devices, angiographic needles, compression devices, scalpels, syringes, tracheobronchial and esophageal stent systems (and accessories), biliary stent systems, endoscopic guidewires, balloon catheters, bipolar coagulation probes, stent positioning system intended for coronary or renal interventional procedures, peritoneal dialysis catheters, accessories kits, embolization particles, biopsy instruments and accessories, vascular grafts and graft accessory component kits, orthopedic bone cement, bone cement delivery devices/accessories, orthopedic surgical instruments, inflatable balloon tamps, endovascular stent grafts, RF tumor ablation systems for orthopedic applications and non-sterile customer specified components for minimally invasive medical devices.



Original Registration Date: 2008-09-05

Latest Revision Date: 2018-12-20

Effective Date: 2017-12-21

Expiry Date: 2020-12-20

Page: 2 of 4

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Certificate No: **FM 534441**

Location

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

Registered Activities

The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) including angiographic, angioplasty and other procedure kits/packs, angiographic catheters, vascular catheters, peripheral catheters, guiding catheters, guidewires (coated and uncoated), introducer needles, angiographic needles, trocars, hemodialysis catheters, introducer devices, dilators, transducers, drainage devices, contrast management devices, embolectomy devices, inflation systems (analog and digital), scalpels, torque devices, tubing, manifolds/stopcocks, valves, syringes, waste disposal, tracheobronchial and esophageal stent systems (and accessories), biliary stent systems, balloon catheters, bipolar coagulation probes and all related accessories, stent positioning system intended for coronary or renal interventional procedures, peritoneal dialysis catheters, accessories and kits, embolization particles, biopsy instruments and accessories, vascular grafts and graft accessory component kits, and orthopedic surgical instruments, inflatable balloon tamps, endovascular stent grafts, and RF tumor ablation systems for orthopedic applications.

Merit Medical Ireland Ltd  
Parkmore Business Park West  
Galway  
Ireland

The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) for infusion, drainage angiography needles, analog inflation devices, occluding guidewires, guide wires (coated and uncoated), tubing, stopcocks, manifolds (including high pressure), angioplasty procedure packs containing guidewire insertion tools, hemostasis valves and torque devices, disposal depots, disposal pressure transducers, fluid administration and contrast management sets (with or without adaptors), insertion devices, torque devices, introducer needles, angiographic needles, obturators, temporary sharps holders, waste disposal basins, fluid administration, scalpels, flush devices, endovascular snare devices and accessories, peripheral catheters, orthopedic bone cement, bone cement delivery devices/accessories, biopsy Instruments and accessories, inflatable balloon tamps and RF tumor ablation systems for orthopedic applications and non-sterile customer specified components for minimally invasive medical devices.

Original Registration Date: 2008-09-05

Effective Date: 2017-12-21

Latest Revision Date: 2018-12-20

Expiry Date: 2020-12-20

Page: 3 of 4

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To be read in conjunction with the scope above or the attached appendix.

Certificate No: **FM 534441**

Location	Registered Activities
Merit Medical Systems, Inc. 1375 West 8040 South West Jordan Utah 84088 USA	The manufacture and packaging of sterile medical devices including balloon catheters and compression devices.
Merit Holdings, Inc. Amerikalaan 42 6199 AE Maastricht-Airport The Netherlands	Customer service, labeling and distribution.
Merit Medical Systems, Inc. 14646 Kirby Drive Houston Texas 77047 USA	Design, development, manufacture, packaging, and distribution of sterile medical devices including catheters and guide catheters (braided and non-braided), (single and multipack), introducers (vascular and non-vascular), dilators (vascular and non-vascular), tracheobronchial and esophageal stent systems (and accessories), biliary stent systems and associated kits (single and multipack) for angiography, drainage, coronary and peripheral applications.
Merit Maquiladora México, S. DE R.L. DE C.V. Avenida Sor Juana Inés de la Cruz 19970 interior B, Edificio 2 Parque Industrial Frontera Tijuana, Baja California C.P. 22630 Mexico	The design, development, manufacture, packaging and distribution of sterile medical devices including infusion devices, catheter and guide catheters, fixation devices, vascular & non-vascular Introducers and dilators, scalpels, biopsy instruments and accessories, Waste disposal Systems, Sharps Holders, Fluid Administration/Handling devices (including High and Low Pressure ? Tubing, Manifolds, Compression Devices and Contrast Management devices (Systems and Kits).

Original Registration Date: 2008-09-05

Effective Date: 2017-12-21

Latest Revision Date: 2018-12-20

Expiry Date: 2020-12-20

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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

**Specificații de pret (F4.2)**

[Acest tabel va fi completat de către ofertant în coloanele 5,6,7,8, iar de către autoritatea contractantă – în coloanele 1,2,3,4,9,10]

Numărul procedurii de achiziție ocds-b3wdp1-MD-1568096290879

Denumirea procedurii de achiziție: Achiziționarea consumabilelor angiografice pentru anul 2019

Cod CPV	Nr. Lot	Denumirea bunurilor	Unitatea de măsură	Cantitatea	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma (fără TVA) □	Suma (cu TVA)	Termenul de livrare	Clasificati e bugetara (IBAN)
1		2	3	4	5	6	7	8,00	9	10
33141200-2	1	Catetere de diagnostic femurale și radiale	buc	100	250,00	270,00	25 000,0000	27000,00	in decurs de 10 zile de la comanda efectuata	
							25 000,0000	27000,00		

Semnat: "electronic" Numele, Prenumele: Raicu Alexandru În calitate de: Administrator

Ofertantul: Life Med SRL Adresa: mun. Chisinau str. Tudor Strisca 30

**Specificații tehnice (F4.1)**

Numărul procedurii de achiziție ocds-b3wdp1-MD-1568096290879

**Denumirea procedurii de achiziție: Achiziționarea consumabililor angiografice pentru anul 2019**

Cod CPV	Num ar lot	Denumirea bunurilor	Modelul articolului	Țara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referință
1	2	3	4	5	6	7	8	
33141200-2	1	Catetere de diagnostic femurale și radiale	Performa	SUA	Merit Medical	Fabricate din nylon - elastomer sau nylon - poliuretan, cu varf atraumatic Diametre : 4 F(extern:1.40mm, intern :1.03mm), 5F(extern:1.70mm, intern: 1.20mm) și 6 F(extern:2.00mm, intern 1.30mm) Lungimi: 65 cm, 80 cm, 90 cm, 100 cm, 110 cm Control optim al torsiunii și radioopacitate sporită prin armare internă "double mesh", cu fire de oțel inoxidabil de 50 micrometri Presiunea de lucru 1000 psi, pentru 5 Fr- 750 psi și pentru 4 Fr - 1200 psi. La aceasta presiune fluxurile substanței de contrast la 37 grade Celsius și la un cateter selectiv de 100 cm prin care se injectează 60 ml substanță sunt: pentru cateterul de 4F 15.0 ml/s, pentru cel de 5F 22.6 ml/s, iar pentru cel de 6F 25.6 ml/s astfel: pentru cateterul de 4F 10.0 ml/s, pentru cel de 5F 22.6 ml/s, iar pentru cel de 6F 25.6 ml/s Lungimi: 80, 100 sau 110 cm Hub din plastic, transparent cu profil de intrare conic, luer-lock Rezistentă la împingere și răsucire Formele uzuale plus următoarele forme speciale: IM EL GAMAL COE 2 Yashiro TIG I TIG II BLK	Fabricate din nylon - elastomer sau nylon - poliuretan, cu varf atraumatic Diametre : 4 F(extern:1.40mm, intern :1.03mm), 5F(extern:1.70mm, intern: 1.20mm) și 6 F(extern:2.00mm, intern 1.30mm) Lungimi: 65 cm, 80 cm, 90 cm, 100 cm, 110 cm Control optim al torsiunii și radioopacitate sporită prin armare internă "double mesh", cu fire de oțel inoxidabil de 50 micrometri Presiunea de lucru 1000 psi, pentru 5 Fr- 750 psi și pentru 4 Fr - 1200 psi. La aceasta presiune fluxurile substanței de contrast la 37 grade Celsius și la un cateter selectiv de 100 cm prin care se injectează 60 ml substanță sunt: pentru cateterul de 4F 15.0 ml/s, pentru cel de 5F 22.6 ml/s, iar pentru cel de 6F 25.6 ml/s astfel: pentru cateterul de 4F 10.0 ml/s, pentru cel de 5F 22.6 ml/s, iar pentru cel de 6F 25.6 ml/s Lungimi: 80, 100 sau 110 cm Hub din plastic, transparent cu profil de intrare conic, luer-lock Rezistentă la împingere și răsucire Formele uzuale plus următoarele forme speciale: IM EL GAMAL COE 2 Yashiro TIG I TIG II BLK	CE

Semnat: "electronic" Numele, Prenumele: Raicu Alexandru În calitate de: Administrator

Ofertantul: Life Med SRL  
Adresa: mun. Chisinau, str.  
Tudor Strisca 30



## Formularul ofertei (F3.1)

Data depunerii ofertei: "18" Septembrie 2019

Procedura de achiziție Nr.: ocde-b3wdp1-MD-1568096290879

Către: IMSP Institutul de Medicina Urgenta

Life Med SRL declară că:

- a) Au fost examinate și nu există rezervări față de documentele de atribuire, inclusiv modificările
- b) Life Med SRL se angajează să  
  
furnizeze în conformitate cu documentele de atribuire și condițiile stipulate în specificațiile tehnice și preț, următoarele bunuri consumabile angiografie
- c) Suma totală a ofertei fără TVA constituie:  
25 000.00 ( Douazeci si cinci mii) LEI.
- d) Suma totală a ofertei cu TVA constituie:  
27 000.00 ( Douazeci si sapte mii) Lei.
- e) Prezenta ofertă va rămâne valabilă pentru perioada de timp specificată în **FDA3.8.**, începînd cu data-limită pentru depunerea ofertei, în conformitate cu **FDA4.2.**, va rămîne obligatorie și va putea fi acceptată în orice moment pînă la expirarea acestei perioade;
- f) În cazul acceptării prezentei oferte, Life Med SRL se angajează să obțină o Garanție de bună execuție în conformitate cu **FDA6**, pentru executarea corespunzătoare a contractului de achiziție publică.
- g) Nu sîntem în nici un conflict de interese, în conformitate cu art. 74 din Legea nr. 131 din 03.07.2015 privind achizițiile publice.
- h) Compania semnatară, afiliații sau sucursalele sale, inclusiv fiecare partener sau subcontractor ce fac parte din contract, nu au fost declarate neeligibile în baza prevederilor legislației în vigoare sau a regulamentelor cu incidență în domeniul achizițiilor publice.

Semnat: „electronic”

Nume: Raicu Alexandru

În calitate de: Administrator

Ofertantul: Life Med SRL

Adresa: RM, Mun. Chisinau, str. Tudor Strisca 30

Data: "18" Septembrie 2019





**LISTA Fondatorilor LA DATA DE 18.09.2019**

***"Life Med" SRL c/f 1014600035666  
mun. Chisinau, str. Tudor Strisca 30***

<b>Nr. d/o</b>	<b>Numele, Prenumele</b>	<b>Cod personal</b>	<b>Cota parte</b>
1	Girnet Serghei	0970103043438	100,00%

**Administrator**

Raicu Alexandru \_\_\_\_\_

**ORDIN DE PLATA**

1572

DATA EMITERII

18 septembrie 2019

TIP DOC : 1

**PLATITI:** 600-00 LEI Șase Sute LEI și 00 Ban**PLĂTITOR** (R) LIFE MED SRL

CODUL IBAN

MD21AG000000022512407485

COD FISCAL:

1014600035666

PRESTATORUL PLĂTITOR: BC'MOLDOVA-AGROINDBANK'S.A. suc.nr.16 Chisinau

**BENEFICIAR** (R) IMSP Institutul de Medicina Urgenta

CODUL IBAN

MD55VI022510300000002MDL

COD FISCAL:

1003600152606

PRESTATORUL BENEFICIAR: B.C.'VICTORIABANK'S.A.

DESTINAȚIA PLĂȚII: Achitarea garantiei pentru oferta Licitatie nr. ocds-b3wdp1-MD-1568096290879 din 19.09.2019TIPUL TRANSFERULUI  
NORMAL/URGENT

N

L.S.

COD TRANZACȚIE:

DATA PRIMIRII:

DATA EXECUTĂRII:

001

18 septembrie 2019 14:40:00

18 septembrie 2019 14:40:00

SEMNĂTURILE EMITENTULUI

SEMNĂTURA PRESTATORULUI

L.Ș.

MOTIVUL REFUZULUI:

**DECLARAȚIE**  
privind prezentarea mostrelor

Data: 18.09.18

Licitația nr.: *ocds-b3wdp1-MD-1568096290879*

Către: *IMSP Institutul de Medicina Urgenta*

Prin prezenta, „LIFE MED” SRL se obliga sa prezinte mostre, la solicitare in termen de 5 zile.

Semnat: „electronic”

Nume: Raicu Alexandru

Funcția în cadrul firmei: Administrator

Denumirea firmei și sigiliu: „LIFE MED” SRL