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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Dongguan Kewei Medical Instrument Co., Ltd.
No. 5 Tongqing Road
Dongcheng District
Dongguan City
Guangdong
523127
China

东莞科威医疗器械有限公司
中国
广东省
东莞市
东城区
同庆路5号
邮编：523127

Holds Certificate No: **MD 613000**

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

The design, development and manufacture of Sterile Venous Return Cannula, Arterial Cannula, Cardioplegia circuit cannula and Suction catheter. The manufacture of Sterile Arterial Filters, Cardioplegia Delivery Systems, Membrane Oxygenation Systems ,Endotracheal Tubes, Patent Ductus Arteriosus (PDA) Occluder and Delivery Systems, Atrial Septal Defect (ASD) Occluder and Delivery Systems ,Ventricular Septal Defect (VSD) Occluder and Delivery Systems.
静脉插管和动脉插管、心肌保护液灌注装置配管、吸引管等无菌产品的设计、开发和制造。动脉微栓过滤器、心肌保护液灌注装置、膜式氧合器、气管插管、动脉导管未闭封堵器及输送系统、房间隔缺封堵器及输送系统、室间隔缺损封堵器及输送系统等无菌产品的制造。

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-12-09
Latest Revision Date: 2018-10-30

Effective Date: 2018-12-09
Expiry Date: 2021-12-08

Digitally signed by Iarovoi Petru
Date: 2020.04.30 12:25:47 EEST
Reason: MoldSign Signature
Location: Moldova

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EC Design-Examination Certificate

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

No. **CE 623392**

Issued To: **Dongguan Kewei Medical Instrument Co., Ltd.**
No.5 Tongqing Road
Dongcheng District
Dongguan City
Guangdong
523127
China

In respect of:

Venous Return Cannula

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-09-22** Date: **2018-04-25** Expiry Date: **2022-09-21**

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EC Design-Examination Certificate

Supplementary Information to CE 623392

Issued To:

Dongguan Kewei Medical Instrument Co., Ltd.
No.5 Tongqing Road
Dongcheng District
Dongguan City
Guangdong
523127
China

Venous Return Cannula: catalogue numbers list

Product Size	Single stage			Two stage	
	Straight plastic tip	Angled plastic tip	Angled metal tip	Round lumen	Oval lumen
Fr12	VC-PSR-12	VC-PCR-12	VC-MCR-12	/	/
Fr14	VC-PSR-14	VC-PCR-14	VC-MCR-14	/	/
Fr16	VC-PSR-16	VC-PCR-16	VC-MCR-16	/	/
Fr18	VC-PSR-18	VC-PCR-18	VC-MCR-18	/	/
Fr20	VC-PSR-20	VC-PCR-20	VC-MCR-20	/	/
Fr22	VC-PSR-22	VC-PCR-22	VC-MCR-22	/	/
Fr24	VC-PSR-24	VC-PCR-24	VC-MCR-24	/	/
Fr26	VC-PSR-26	VC-PCR-26	VC-MCR-26	/	/
Fr28	VC-PSR-28	VC-PCR-28	VC-MCR-28	/	/
Fr30	VC-PSR-30	VC-PCR-30	/	/	/
Fr32	VC-PSR-32	VC-PCR-32	/	/	/
Fr34	VC-PSR-34	VC-PCR-34	/	/	/
Fr36	VC-PSR-36	VC-PCR-36	/	/	/
Fr38	VC-PSR-38	VC-PCR-38	/	/	/
Fr40	VC-PSR-40	VC-PCR-40	/	/	/
Fr42	VC-PSR-42	VC-PCR-42	/	/	/
Fr24/28	/	/	/	VC-TSR-2428	VC-TSO-2428
Fr28/36	/	/	/	VC-TSR-2836	VC-TSO-2836
Fr30/38	/	/	/	VC-TSR-3038	VC-TSO-3038
Fr32/38	/	/	/	VC-TSR-3238	VC-TSO-3238
Fr34/38	/	/	/	VC-TSR-3438	VC-TSO-3438
Fr34/40	/	/	/	VC-TSR-3440	VC-TSO-3440
Fr34/46	/	/	/	VC-TSR-3446	VC-TSO-3446
Fr34/48	/	/	/	VC-TSR-3448	VC-TSO-3448
Fr36/46	/	/	/	VC-TSR-3646	VC-TSO-3646
Fr36/50	/	/	/	VC-TSR-3650	VC-TSO-3650
Fr38/50	/	/	/	VC-TSR-3850	VC-TSO-3850

First Issued: **2017-09-22** Date: **2018-04-25** Expiry Date: **2022-09-21**

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China

Certificate History

Date	Reference Number	Action
22 September 2017	8436827	First issue.
Current	8848294	Addition of two stage venous return cannula catalogue numbers VS-TSR-2428 to VS-TSO-3850.

First Issued: **2017-09-22** Date: **2018-04-25** Expiry Date: **2022-09-21**

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