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# 中国国际贸易促进委员会



China Council for the Promotion of International Trade  
China Chamber of International Commerce

## 证明书

CERTIFICATE



221100B0/013321

号码 No.

兹证明：所附中华人民共和国医疗器械产品出口销售证明的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS OF THE PEOPLE'S REPUBLIC OF CHINA is in conformity with the original.



China Council for the Promotion  
of International Trade

授权签字:

Lyu Cuilian

Authorized  
Signature:

日期: 2022年03月15日

(Date: Mar. 15, 2022)



中华人民共和国  
PEOPLE'S REPUBLIC OF CHINA  
医疗器械产品出口销售证明  
CERTIFICATE FOR EXPORTATION OF MEDICAL  
PRODUCTS

证书编号: 津食药监械出20220038号

Certificate: 津食药监械出20220038号

产品名称: 见附件

Product(s): SEE ATTACHMENT

规格型号: 见附件

Model: SEE ATTACHMENT

产品注册或备案凭证号: 见附件

Registration certificate(s): SEE ATTACHMENT

生产企业: 天津怡和嘉业医疗科技有限公司

Manufacturer: BMC(Tianjin) Medical Co., Ltd.

生产企业住所: 天津市武清开发区新兴路1号4-3; 天津市武清开发区新兴路1号4-2  
北侧

Address of manufacturer: 2/F North Area and 3/F, Building No.4, No.1 Xi  
nxing Road, Wuqing District, 301700 Tianjin, CHINA

生产许可或备案凭证号:

Manufacturing License(s):

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered  
to be manufactured and sold in China.

证明有效日期至: 2023年5月3日

This certification valid until: May. 3<sup>rd</sup>, 2023 .



注: /

Remark: BMC Medical Co., Ltd. (Address: Room 110 Tower A Fengyu Building, No.115 Fucheng Road, Haidian, 100036 Beijing, CHINA) is mother company of BMC(Tianjin) Medical Co., Ltd. (Address: 2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, Tianjin 301700, CHINA), BMC(Tianjin) Medical Co., Ltd. is conducting function of manufacturing for BMC Medical Co., Ltd.



2022年2月14日

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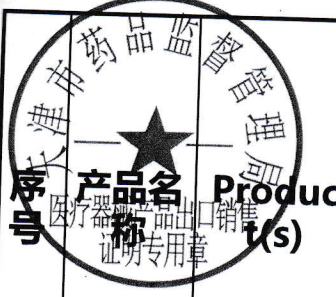
证书编号: 津食药监械出20220038号

附件

Certificate: 津食药监械出20220038号

ATTACHMENT

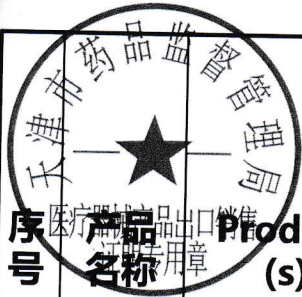
序号	产品名称 Product(s)	规格型号	Model	产品注册或备案凭证号 (Registration certificate)
1	通气面罩 F1B Full Face Mask	F1B	F1B	津械注准 20192080 116
2	通气面罩 iVolve F1A Full Face Mask	BMC-FM1A	BMC-FM1A	津械注准 20192080 116
3	通气面罩 Full Face Mask	F5, F5A, F3	F5, F5A, F3	津械注准 20192080 116
4	通气面罩 iVolve N2 Nasal Mask	BMC-NM2	BMC-NM2	津械注准 20192080 116
5	通气面罩 Nasal Mask	N5, N5A, N5B, N5H, N5A H, N5BH	N5, N5A, N5B, N5H, N5A H, N5BH	津械注准 20192080 116
6	通气面罩 P2 Nasal Pillows Interface	P2	P2	津械注准 20192080 116
7	呼吸管路 Breathing Tube	L1	L1	津械注准 20182660 064
8	呼吸管路 Heated Breathing Tube	GH1, GH2	GH1, GH2	津械注准 20182660 064
9	单水平睡眠呼吸机 RESmart GII Auto CPAP System	E-20A-H-0, E-20AJ-J-0	E-20A-H-0, E-20AJ-J-0	津械注准 20212080 275
10	单水平睡眠呼吸机 Auto CPAP System	G2S A20, G3 A20, M1 Mini	G2S A20, G3 A20, M1 Mini	津械注准 20212080 275



书编号: 津食药监械出20220038号 附件

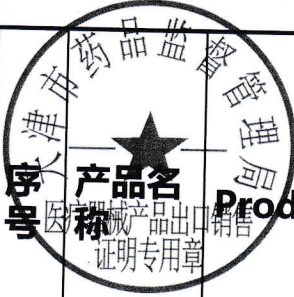
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序号	产品名称 Product (s)	规格型号	Model	产品注册或备案凭证号 (Registration certificate)
11	双水平无创呼吸机 BPAP System	G3 B20A, G3 B25S, G3 B25A, G3 B25VT, G3 B30VT, G3 B30SV, G3 LAB	G3 B20A, G3 B25S, G3 B25A, G3 B25VT, G3 B30VT, G3 B30SV, G3 LAB	津械注准 2019208 0120
12	多导睡眠呼吸监测仪 Portable Sleep Diagnostic System	H2, H2 Plus	H2, H2 Plus	津械注准 2021207 0186
13	双水平无创呼吸机 Respiratory Insufficiency Ventilator	R-80B, R-80C, R-80S	R-80B, R-80C, R-80S	津械注准 2019208 0001
14	双水平无创呼吸机 RESmart GII BPAP System	Y-20T, Y-25T, Y-30T, Y-30AT, U-20T, U-25T, U-30T, U-30AT	Y-20T, Y-25T, Y-30T, Y-30AT, U-20T, U-25T, U-30T, U-30AT	津械注准 2019208 0120
15	通气面罩 iVolve Full Face Mask	BMC-FM	BMC-FM	津械注准 2019208 0116
16	通气面罩 F2 Full Face Mask	BMC-FM2	BMC-FM2	津械注准 2019208 0116
17	通气面罩 F2 NV Full Face Mask	F2 NV1, F2 NV2	F2 NV1, F2 NV2	津械注准 2019208 0116
18	通气面罩 N4 Nasal Mask	NM4	NM4	津械注准 2019208 0116
19	通气面罩 Fealite Nasal Pillows System	BMC-PM	BMC-PM	津械注准 2019208 0116
20	通气面罩 Nasal Pillows Interface	P2H	P2H	津械注准 2019208 0116



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	 产品名称 Product(s)	规格型号	Model	产品注册或备案凭证号 (Registration certificate)	
21	呼吸管路	Heated Breathing Tube	LH1	LH1	津械注准2 01826600 64
22	单水平睡眠呼吸机	RESmart GII CPAP System	E-20C-H-0	E-20C-H-0	津械注准2 02120802 75
23	单水平睡眠呼吸机	CPAP System	G2S C20, G3 C20	G2S C20, G3 C20	津械注准2 02120802 75
24	双水平无创呼吸机	BPAP System	G2S B20S, G2S B20A, G2S B20T, G2S B25S, G2S B25A, G2S B25T, G2S LAB, G2S B25VT, G2S B30T, G2S B30V T, G2S B30AT	G2S B20S, G2S B20A, G2S B20T, G2S B25S, G2S B25A, G2S B25T, G2S LAB, G2S B25VT, G2S B30T, G2S B30V T, G2S B30AT	津械注准2 01920801 20
25	多导睡眠呼吸监测仪	Polysomnograph	H2 Pro, H2 Elite	H2 Pro, H2 Elite	津械注准2 02120701 86
26	高流量湿化氧疗仪	Respiratory High-Flow Therapy Device	H-80M, H-80A, H-80A S	H-80M, H-80A, H-80A S	津械注准2 02020800 19

