

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20210039号

Certificate: 津食药监械出20210039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：天津微纳芯科技有限公司

Manufacturer: Tianjin MNCHIP Technologies Co., Ltd

生产企业住所：天津开发区信环西路19号2号楼2102、2202

Address of manufacturer: 2102, 2202, Building 2, No.19 Xinhuan Rd. West, TEDA, Tianjin, 300457, P.R. China

生产许可或备案凭证号：津食药监械生产许20110342号

Manufacturing License(s): 津食药监械生产许20110342号

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3月22日

This certification valid until: Mar. 22nd, 2023 .

备注：

Remark:



2021年3月23日

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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)
1	肝功能检测冻干试剂盒	Liver Function Panel Lyophilized Kit[8]	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20182400 113
2	肝肾肾功能检测冻干试剂盒	Liver and Renal Function Lyophilized Kit[9]	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20182400 121
3	综合I检测冻干试剂盒	General Chemistry I Lyophilized Kit[13]	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20182400 114
4	肾功能检测冻干试剂盒	Renal Function Panel Lyophilized Kit[7]	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20182400 120
5	糖脂同型半胱氨酸检测冻干试剂盒	GLU & Lipid & HCY Panel Lyophilized Kit[5]	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20192400 027
6	综合III检测冻干试剂盒	General Chemistry III Lyophilized Kit[13]	1人份/盘片, 10人份/盒	1 Test / Disc, 10 Discs / Box	津械注准 20202400 101
7	心肌酶检测冻干试剂盒	Myocardial Enzyme Panel Lyophilized Kit[5]	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20182400 118
8	糖脂检测冻干试剂盒	Glucose and Lipid Panel Lyophilized Kit[5]	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20182400 119
9	综合II检测冻干试剂盒	General Chemistry II	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20182400

	剂盒	Lyophilized Kit[8]	0人份/盒。A型不含稀释液, B型含稀释液	B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	115
10	临床急诊检测冻干试剂盒	Clinical Emergency Lyophilized Kit	A型: 1人份/盘片, 10人份/盒; B型: 1人份/盘片, 10人份/盒。A型不含稀释液, B型含稀释液	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container.	津械注准 20182400 117

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	产品名 Product (5)	规格型号	Model	产品注册或备案凭证号 (Registration certificate)
11	电解质检测冻干试剂盒 Electrolyte Panel Lyophilized Kit[7]	A型：1人份/盘片，10人份/盒； B型：1人份/盘片，10人份/盒。 A型不含稀释液，B型含稀释	Type A: 1 Test / Disc, 10 Discs / Box; Type B: 1 Test / Disc, 10 Discs / Box. Type A1: 1 Test / Disc, 10 Discs / Box; Type B1: 1 Test / Disc, 10 Discs / Box. Type A without diluent container; Type B with diluent container. Type A, Type B contains K, Na, Cl, CO2, Ca, Mg, P; Type A1, Type B1 contains K, Na, Cl, Ca.	津械注准20182400116
12	全自动干式生化分析仪 Chemistry Analyzer	Pointcare M1、Pointcare M3、Pointcare M3i、Pointcare M3ix2、Pointcare M3ix4、Pointcare M3ix6、Pointcare M4、Celercare M5	Pointcare M1、Pointcare M3、Pointcare M3i、Pointcare M3ix2、Pointcare M3ix4、Pointcare M3ix6、Pointcare M4、Celercare M5	津械注准20202220099
13	血氨检测冻干试剂盒 Ammonia Panel Lyophilized Kit[1]	1人份/盘片，10人份/盒	1 Test / Disc, 10 Discs / Box	津械注准20202400125