



### 1.2.1 The certificate of pharmaceutical product

See Annex

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摩尔多瓦 双 E  
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210165451-001 1/3 ⑦  
摩尔多瓦 EDC  
2021/08/09 002

# 证明书

## CERTIFICATE



# 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



号码 No. 211100B0/047038

兹证明：在所附中华人民共和国药品出口销售证明上的山东省药品监督管理局药品出口销售证明专用章（6）属实。

THIS IS TO CERTIFY THAT: the special seal (6) for EXPORT SALE CERTIFICATE OF DRUG of SHANDONG DRUG ADMINISTRATION on the annexed CERTIFICATE OF A PHARMACEUTICAL PRODUCT OF THE PEOPLE'S REPUBLIC OF CHINA is genuine.

China Council for the Promotion  
of International Trade

授权签字:

Authorized  
Signature: Lyu Cuilian

日期: 2021年07月22日  
(Date: Jul. 22, 2021)

# 中华人民共和国

PEOPLE'S REPUBLIC OF CHINA

## 药品出口销售证明

CERTIFICATE OF A PHARMACEUTICAL PRODUCT



(已在中国批准上市药品)

(Pharmaceutical Product Approved in China)

This certificate conforms to the format recommended by the World Health Organization.  
该证明符合世界卫生组织 (WHO) 推荐的格式。

证书编号 (Certificate No.)	中文: 鲁 20210111 (6)
	英文: No.Shandong20210111 (6)
进口国/地区(提出要求的国家/地区) Importing Country /Region (Requesting Country /Region)	中文: 摩尔多瓦共和国
	英文: The Republic of Moldova
产品名称与剂型 Name and Dosages Form of the Product	中文: 乳酸钠林格注射液; 剂型: 注射剂
	英文: Sodium Lactate Ringer's Injection (Lactated Ringer's Injection); Dosage form: Solution for Injection
商品名 Trade Name	中文: 不适用
	英文: Not Applicable
活性成分与规格[不对外公开] Active Ingredient(s) and Strength[Not disclosed to the public]	中文: 每瓶(500mL) 含 1.55g 乳酸钠, 3g 氯化钠, 0.15g 氯化钾, 0.1g 氯化钙
	英文: Each bottle(500ml) contains 1.55g of Sodium Lactate,3g of Sodium Chloride,0.15g of Potassium Chloride,0.1g of Calcium Chloride
包括辅料在内的完整处方组成(可附表)[不对外公开] For complete composition including excipients, see attached[Not disclosed to the public]	中文: 每瓶(500mL) 含 1.55g 乳酸钠, 3g 氯化钠, 0.15g 氯化钾, 0.1g 氯化钙, 加注射用水至 500ml。
	英文: Each bottle (500ml) contains 1.55g of Sodium Lactate, 3g of Sodium Chloride, 0.15g of Potassium Chloride, 0.1g of Calcium Chloride and add Water for Injection to 500ml .

<p>该药品规格是否获得许可在出口国市场上使用 Is this product strength licensed to be placed on the market for use in the exporting country</p>	<p>是 (Yes) ( <input checked="" type="checkbox"/> )</p>	
<p>该药品规格是否已经在出口国市场上使用 Is this product strength actually on the market in exporting country</p>	<p>是 (Yes) ( <input checked="" type="checkbox"/> ) 否 (No) ( <input type="checkbox"/> )</p>	
<p>产品批准文号 (原料药备案号) 及批准 (备案) 时间 Number of product license (DMF number) and date of issue</p>	<p>中文: 国药准字 H20057107, 2020-04-24</p>	
	<p>英文: GYZZ H20057107, Apr. 24, 2020</p>	
<p>药品生产企业或者药品上市许可持有人 (名称和地址) Manufacturer or Product-license holder (name and address)</p>	<p>名称 Name</p>	<p>中文: 辰欣药业股份有限公司</p>
	<p>名称 Name</p>	<p>英文: Cisen Pharmaceutical Co.,Ltd.</p>
	<p>地址 Address</p>	<p>中文: 中国山东省济宁市高新区同济科技工业园</p>
		<p>英文: Tongji Tech Industry garden, Jining High &amp; New Technology Industries Development Zone, Jining, Shandong Province, P.R.China.</p>
<p>如果药品上市许可持有人不是生产者, 药品实际生产者是谁 If the license holder is not the manufacturer, the name and address of the manufacturer producing the dosage form is</p>	<p>生产者 Manufacturer</p>	<p>中文: 不适用</p>
	<p>生产者 Manufacturer</p>	<p>英文: Not applicable</p>
	<p>地址 Address</p>	<p>中文: 不适用</p>
	<p>地址 Address</p>	<p>英文: Not applicable</p>
<p>证明当局是否对该药品的实际生产企业进行定期检查 Does the certifying authority arrange for periodic inspections of the manufacturing plant in which the dosage form is produced</p>	<p>是 (Yes) ( <input checked="" type="checkbox"/> )</p>	

定期检查的周期 Periodicity of routine inspections (years)	一年 One year	
生产设备和操作是否中国药品生产质量管理规范的要求 Do the facilities and operations conform to the requirements of Chinese GMP	是 (Yes) (√)	
<p>兹证明上述产品符合中华人民共和国有关标准，已在中国注册，准许在中国市场销售。该产品出口不受限制。</p> <p>This is to certify that the above product(s) comply with the relevant standards of the P. R. China, have been registered and authorized to be sold in China. The exportation of the product(s) is not restricted.</p>		
证明的有效期至 This certificate remain valid until	2023年05月06日 May. 06, 2023	
证明当局 Certifying authority	名称 Name	中文：山东省药品监督管理局区域检查第六分局 英文：The Sixth Branch of Regional Inspection of Shandong Medical Products Administration
	地址 Address	中文：菏泽市经济开发区郑州路888号1号楼 英文：1st Building, No. 888 Zhengzhou Road, Economic Development Zone, Heze City
	电话 Telephone number	0086 530 5699072
	传真 Fax	0086 530 5699075
	签字 Signature	
	签章与日期 Stamp and date	 2021-05-07

此证明仅在进口国/地区进行药品注册使用。

This certificate is only for registration of pharmaceutical products in the importing country/region.

山东省药品监督管理局  
销售证明  
章  
6)

INTERNATIONAL TRADE

认字第210165451-001号

兹证明前面文书上中国国际贸易促进委员会商事证明专用章和授权签字人(吕翠连)的签字属实。



中华人民共和国外交部  
领事司一等秘书  
二〇二一年七月二十三日

朱岭

01813373

The Embassy of the Republic of Moldova  
to the People's Republic of China  
authenticates the preceding signature and stamp  
no. 228  
27.07 2021  
Martalia Dima, First Secretary  
Name, surname  
Position  
The Embassy of the Republic of Moldova  
is not responsible for the content of the document.



Handwritten signature