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Date: 2023.08.15 08:30:37 EEST
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Location: Moldova

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：苏 20230093 号 英文：No.Jiangsu20230093	
进口国/地区(提出要求的国家/地区)[不对外公开] Importing Country /Region (Requesting Country /Region)[Not disclosed to the public]	中文：摩洛哥 英文：Morocco	
产品名称与剂型 Name and Dosages Form of the Product	中文：注射用英夫利西单抗 注射剂 英文：Infliximab for injection Injection	
商品名 Trade Name	中文：类停 英文：Reminton	
活性成分与规格[不对外公开] Active Ingredient(s) and Strength[Not disclosed to the public]	中文：英夫利西单抗 100mg/瓶 英文：Infliximab 100mg/vial	
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： 英夫利西单抗，磷酸氢二钠，磷酸二氢钠，蔗糖，聚山梨酯 80，注射用水 英文：Infliximab, disodium hydrogen phosphate, sodium dihydrogen phosphate, surcose, tween 80, water for injection	
该药品规格是否获得许可在中国市场上使用 Is this product strength licensed to be placed on the market for use in China	是（Yes）	
该药品规格是否已经在中国国市场上使用 Is this product strength actually on the market in China	是（Yes）	
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	中文：国药准字 S20210025 2021-07-12 英文：S20210025 2021-07-12	
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)	名称 Name	中文：泰州迈博太科药业有限公司 英文：Taizhou Mabtech Pharmaceuticals Co., Ltd
	地址 Address	中文：江苏省泰州市泰州医药高新技术产业开发区江苏省泰州市中国医药城口泰路西侧、陆家路东侧 G79 幢 英文：G79 Building, East of Lujia Road and West of Koutai Road, Chinese Medicine Center, Taizhou, Jiangsu, China

<table>
<tr><td rowspan="3">如果药品上市许可持有人不是生产者，药品实际生产者是
If the license holder is not the manufacturer, the name and address of the manufacturer producing the dosage form is</td><td>生产者
Manufacturer</td><td>中文：泰州迈博太科药业有限公司</td></tr>
<tr><td></td><td>英文：Taizhou Mabtech Pharmaceuticals Co., Ltd</td></tr>
<tr><td>地址
Address</td><td>中文：江苏省泰州市泰州医药高新技术产业开发区江苏省泰州市中国医药城口泰路西侧、陆家路东侧 G79 幢
英文：G79 Building, East of Lujia Road and West of Koutai Road, Chinese Medicine Center, Taizhou, Jiangsu, China</td></tr>
<tr><td>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</td><td colspan="2">是（Yes）</td></tr>
<tr><td>定期检查的周期（年）
Periodicity of routine inspections (years)</td><td colspan="2">1</td></tr>
<tr><td>此类剂型的生产是否检查过
Has the manufacture of this type of dosage form been inspected</td><td colspan="2">是（Yes）</td></tr>
<tr><td>生产设备和操作是否符合 WHO 推荐的药品生产质量管理规范
Do the facilities and operations conform to GMP as recommended by the World Health Organization</td><td colspan="2">是（Yes）</td></tr>
<tr><td>申请人所提供的信息是否满足证明当局的要求
Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product</td><td colspan="2">是（Yes）</td></tr>
<tr><td colspan="3">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。
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.</td></tr>
<tr><td>证明的有效期至
This certificate remain valid until</td><td colspan="2">2025-03-06</td></tr>
<tr><td rowspan="7">证明当局
Certifying authority</td><td>名　称
Name</td><td>中文：江苏省药品监督管理局
英文：Jiangsu Medical Products Administration</td></tr>
<tr><td>地　址
Address</td><td>中文：江苏省南京市鼓楼街 5 号
英文：No.5 Gulou Street, Nanjing City, Jiangsu Province, P.R. China</td></tr>
<tr><td>电　话
Telephone number</td><td>025-83209373</td></tr>
<tr><td>传　真
Fax</td><td>025-83278888</td></tr>
<tr><td>签　字
Signature</td><td></td></tr>
<tr><td>签章与日期
Stamp and date</td><td>2023-03-07</td></tr>
</table>