中华人民共和国
浙江省药品监督管理局
出口欧盟原料药证明文件

PEOPLE'S REPUBLIC OF CHINA
ZHEJIANG MEDICAL PRODUCTS ADMINISTRATION
Written confirmation for active substances exported to EU

Confirmation no.(given by the issuing regulatory authority):ZJ220039
证明文件编号：ZJ220039

1. Name and address of site (including building number, where applicable):Zhejiang Hengkang Pharmaceutical Co., Ltd. No.11 Chengen Road, Pubagang Town, Sanmen, Zhejiang, China 317108
工厂名称与地址(包括建筑物门牌号)：浙江恒康药业股份有限公司 浙江省三门县浦坝港镇承恩路11号

2.Manufacturer's licence number(s):浙20060453
《药品生产许可证》编号：浙20060453

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE
项目1所列生产企业生产的下列用于出口欧盟的人用原料药

Active substance(s) 原料药名称（药品通用名）	Activity(ies) 加工方法	Chinese drug approval number[1] 中国药品批准文号
Mesalazine,美沙拉秦	Chemical synthesis,1	无

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:
兹证明:
This manufacturing plant complies with the requirements of the Chinese Good Manufacturing Practice (= GMP of EU，WHO/ICH Q7);
该企业所实施的GMP符合中国药品GMP要求，等同于欧盟、世界卫生组织组织以及ICH Q7药品GMP要求;

[1]仅供出口的原料药在此栏填写“无”。
Record “none” in case where there is for export-only active substance.

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure the protection of public health ,which is at least equivalent to that in the EU; and

该生产工厂接受定期、严格和透明的监管以及有效地执行药品GMP监管措施，包括反复的飞行检查，确保保护公众健康，其水平与欧盟相当；并且

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.
如发现不合规情况，将会及时通报欧盟有关部门。

Date of inspection of the plant under (1):Sep 27th, 2021
对该生产工厂检查的日期：2021年09月27日

This written confirmation remains valid until:Dec 15th, 2024
本证明文件的有效期：2024年12月15日

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
关于本证明文件的可靠性可向本局查询确认。

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Chinese law and Directive 2001/83/EC.
按照中国相关法律以及欧盟2001/83/EC指令，生产者应对药品质量负责，本证明不影响生产者履行该职责。

Address of the issuing regulatory authority: 27Wenbei Lane Mogansan Road Hangzhou 310012 P.R.China
签发部门地址：杭州莫干山路文北巷27号

Name and function of responsible person: He JinHua , Deputy Director
负责人姓名及职务：何金华，副处长

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Signature	Stamp of the authority and date:Apr 28th, 2022

签字 	签发部门盖章与日期：2022年04月28日