

食品经营许可证

经 营 者 名 称:东莞市宏业博艾生物科技有限公司

统一社会信用代码:91441900MA4WN4C14N

(身份证号码)

法定代表人(负责人):王洪军

住 所:广东省东莞市南城街道黄金路1号3栋1单

所:广东省东莞市南城街道黄金路1号3栋1单

本:食品销售经营者(网络经营、食品贸易商:食品代理销售商)

目:特殊食品销售(保健食品零售): 预包装食品销售(不含预包装冷藏 冷冻食品) 经

许可证编号: JY14419192524896

日常监督管理机构:南城分局

日常监督管理人员:宋海斌,周蓓菁

投诉举报电话: 12315

发 证 机 关: 东莞市市场监督管理局



有效期至 2025 年07 月29 日



ISET S.r.I. Unipersonale

Sede Legale e Uffici Via Donatori di sangue, 9 - 46024 Moglia (MN) TeL e fax +39 (0)376 598963

Cod. Fisc. e P.NA Reg. Imprese 02332750369 REA 02332750369

Cap. soc. iv.

www.iset-italia.com commercialef@iset-italia.com

Cap. soc. Lv. MN 0221098

CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

APPLICANT: (who finally puts the product on the market)
 Guangzhou Huaizhong Medical Co.,Ltd
 No.103,Ruyi 3rd Road,Luoxi New Town,Luopu Street,Panyu District,Guangzhou

CERTIFICATE NO.: ISETC.000920210107
 TECHNICAL REFERENCE: TCF-03-2020312-REACH

3) ISET MARK:



4) CAUTION ABOUT CE MARKING (Instruction for the Applicant who puts the product on the EU market):

The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

- TYPE OF PRODUCT: MEDICAL INSTRUMENT VAGINAL GEL MODEL(S): I:Haojin 3G/A, II:Dongtingmei 3G/A
- LIST OF DIRECTIVES / REGULATIONS /STANDARDS (as declared by the manufacturer itself)
 REGULATION concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) 1907/2006
 EN 1276:2019
- NOTE: This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.
- 8) REMARK: Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.

9) DATE OF ISSUE: 07/01/2021

10) SIGNATURE: Xiao Ming

EXPIRY DATE: 06/01/2026





统一社会信用代码

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营业执照



扫描二维码登录" 国家企业信用信息 公示系统"了解更 多登记、备案、许 可、监管信息。

名 称 东莞市宏业博艾生物科技有限公司

法定代表人 王洪军

经营范围

生物技术研发;生产:食品:销售、网上销售:特殊食品(保健食品)、美容用品、初级农产品、预包装食品、第一类医疗器械、第二类医疗器械、劳保用品;生态农业、中医药、土地改良、教育器材、教育课程研发;教育咨询;文化交流活动策划;会议及展览服务;生物技术推广、技术咨询;新材料技术推广;企业管理咨询;企业形象策划;市场信息咨询、市场营销策划;广告设计、制作、发布;会展服务,礼仪活动交流策划;从事网络科技专业领域内技术开发;计算机软硬件开发;计算机技术开发、技术咨询、技术服务、技术转让;信息技术开发、知识产权代理。(依法须经批准的项目,经相关部门批准后方可开展经营活动。)

注册资本 人民币壹仟万元

成立日期 2017年06月08日

营业期限长期

庁 广东省东莞市南城街道黄金路1 号3栋1单元304室

登记机关

请于每年6月30日前报送年度报告,逾期将受到信用惩戒和处罚。 途径: 登录企业信用信息公示系统,或"东莞市场监管"微信公众号。



FISCAL YEAR 2019 CERTIFICATION OF REGISTRATION

This certifies that:

Dongguan Hongye Boai Biotechnology Co., Ltd.

ROOM 1821, JIAJUN CENTER, 76 CHANGDONG ROAD, CHANGPING TOWN, DONGGUAN CITY, GUANGDONG PROVINCE, CHINA

is registered with U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002. P.L.

U.S FDA Registation No :19886182356
U.S Registation Agent :ZBJ NETWORK,INC.

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to section 305 of the U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, such registration having been verified as effective by ZBJ as of the date hereof, and ZBJ will confirm that such registration remains effective upon request and presentation of this certificate until the expiration of one year from the date hereof, unless terminated after issuance of this certificate. ZBJ makes no other presentations or warranties, nor does this certificate make any representation or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. ZBJ assume no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. ZBJ is not affiliated with the U.S. Food and Drug Administration.



