



认证证书

N. CN24-20904H

兹证明

东莞泰克尼迩密封制品有限公司

统一社会信用代码：914419007556175436

注册地址

广东省东莞市常平镇港建路 136 号 15 栋 101 室

办公地址

广东省东莞市常平镇港建路 136 号 15 栋第三层东北侧

生产地址

广东省东莞市常平镇港建路 136 号 15 栋 1 楼洁净室、2 楼、3 楼

完成医疗器械质量管理体系审核并符合以下标准要求

ISO 13485:2016

认证范围：

医疗器械用硅胶和橡胶密封配件的生产和销售

类别：A.1.7

有关此认证证书状态的更多信息，请通过电话+355696037861 / +39 0296368458 联系或发送邮件至 info@axe-register.com 或使用组织名称或证书编号在 www.axe-register.com 网站验证。

该证书须接受定期的年度监督审核和三年一次的完整体系评审确保其有效性。

初次注册日期：2024 年 09 月 11 日

发证日期：2024 年 09 月 11 日

证书有效期至：2027 年 09 月 10 日



CS 007 26.02.18



EA/MLA 签署，多边互认协议

授权人签字
AXE REGISTER Ltd
Antonio Llayda

Antonio Llayda

在证书有效期内每 12 个月内须接受一次监督审核并将监督审核合格标签粘贴于右侧指定位置，此证书方为有效。本证书可在国家认证认可监督管理委员会网站 (www.cnca.gov.cn) 查询。

(1)
监督审核
合格标签
粘贴处

(2)
监督审核
合格标签
粘贴处

AXE REGISTER

中国总部：艾西姆认证（上海）有限公司，中国上海市闵行区外环路 352 号 B201 室，邮政编码：201199

电话：+86 21 64305860 传真：+86 21 64881096 网址：www.acmcert.com.cn 邮箱：info@acmcert.com.cn



CERTIFICATE

N. CN24-20904H

This is to certify that the Quality Management System of Medical Devices of
DONG GUAN TECHNE SEAL MANUFACTURING LTD

Unified social credit code: 914419007556175436

Registered Address

Room 101, Building 15, No.136, Gangjian Road, Changping Town
Dongguan, Guangdong

Office Address

Northeast Side of 3F, Building 15, No.136, Gangjian Road, Changping
Town, Dongguan, Guangdong, China

Production Address

1F Clean Room&2F&3F, Building 15, No.136, Gangjian Road, Changping
Town, Dongguan, Guangdong, China

Has been independently assessed and found in conformance with the standard

ISO 13485:2016

For the following scope of activities:

Production and Sales of Silicone and Rubber Sealing Accessories for Medical Devices

Category: A.1.7

For further and updated information regarding any changes in the status of this certification please contact via phone under +355696037861 / +39 0296368458 or via email to info@axe-register.com or verify directly on the website www.axe-register.com by using the organization name or the certificate number.

The validity of this certificate is subject to periodic yearly surveillance audit and triennial review of the entire management system of the certified organization.

| | |
|-----------------------------------|-------------------|
| Date of first registration | 11/09/2024 |
| Date of this certificate | 11/09/2024 |
| Date of expiry | 10/09/2027 |



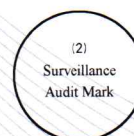
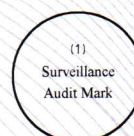
CS 007 26.02.18



On behalf of the Certification Body
AXE REGISTER Ltd
Antonio Llavda
Technical Director

Signatory of EA/MLA, Mutual Recognition Agreements

During validity period of the certificate a surveillance audit should be carried out once within each 12 months. The label should be pasted on specified position of right side of the certificate then it is valid. The certificate can be checked out at CNCA website (www.cnca.gov.cn).



AXE REGISTER

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