世也认证

EVERBIZ Global

医疗器械全球市场准入

Global Marketing Access for Medical Devices

让创新医疗器械走向全球市场

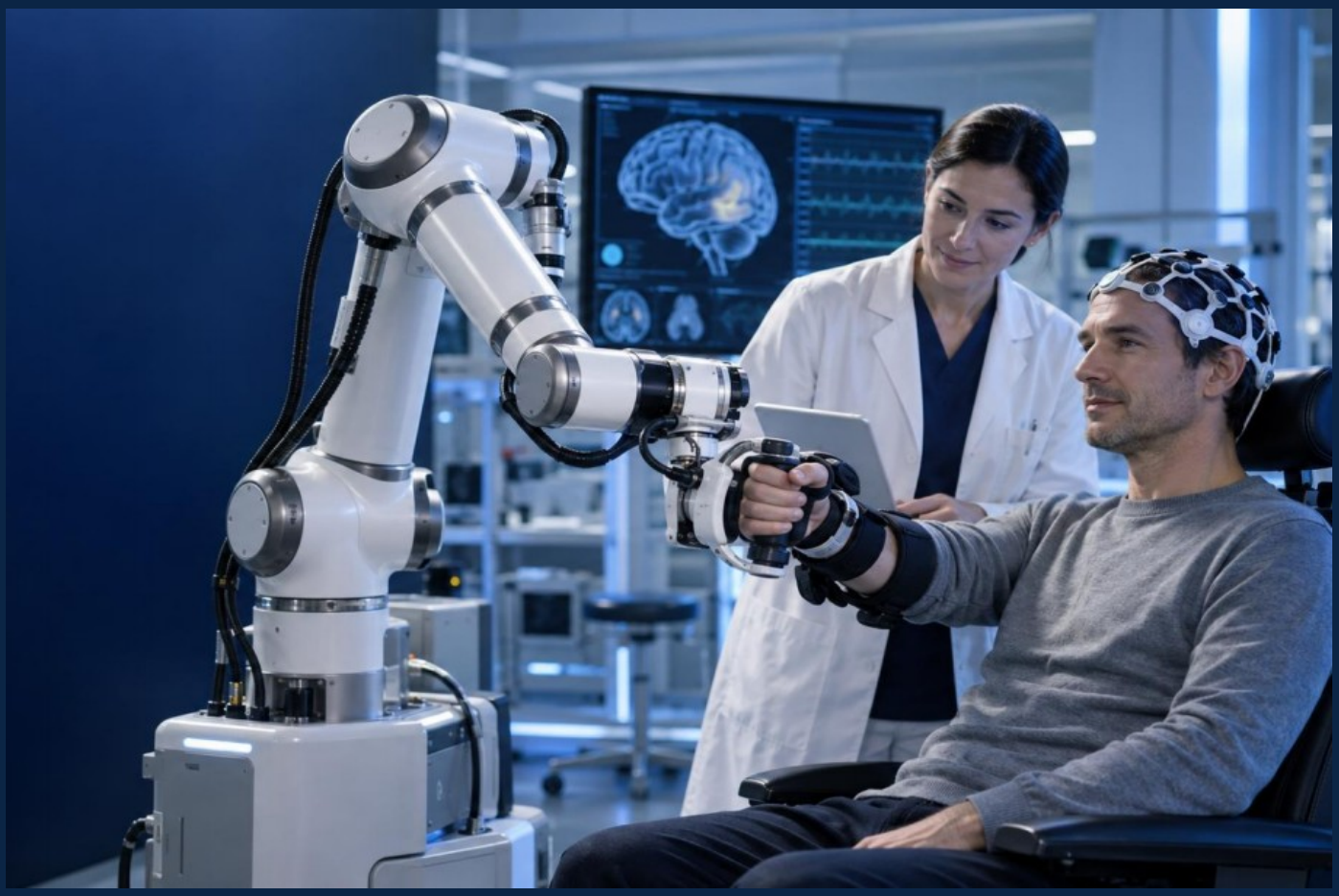
Bringing Innovative Medical Devices to Global Markets

法规注册 · 质量体系 · 测试认证 · 市场准入

Regulatory Registration • Quality Systems • Testing & Certification • Market Access

一站式服务

One stop Services



合规、认证与检测服务

Compliance, certification support and testing

EVERBIZ 公司简介

EVERBIZ Company Profile

世也认证（EVERBIZ）是一家以医疗产品检测、认证、咨询与培训为核心的专业合规服务平台，致力于帮助海内外领先的医疗研发型企业提升合规技能与竞争力。围绕产品研发、注册申报与市场准入， EVERBIZ 整合法规、质量体系及测试资源，为企业提供从需求评估、技术资料准备到项目实施的一站式支持，协助将合规要求落实到研发与上市全过程。

EVERBIZ is a professional compliance service platform specializing in medical product testing, certification support, consulting and training. We help leading medical R&D enterprises in China and abroad to help strengthen their compliance capabilities and competitiveness. Across product development, regulatory submissions and market access, we bring together legislative, quality-system testing resources to provide one-stop support, from needs assessment and technical documentation to project execution, integrating compliance throughout development and launch.

不只是为了法规解读，更是为了将法规要求转化为可执行的项目计划、时间表与交付方案。

Beyond interpreting regulations, we turn requirements into practical project plans, timelines and delivery solutions.

三大服务，衔接全球市场

Integrated Services for Global Market Access

01 合规

Compliance

产品分类与准入路径分析，法规和标准差距评估，技术文件与注册资料辅导，质量体系及临床／性能评价支持。

Classification, market access strategy, regulatory gap assessment, documentation, quality systems and clinical or performance evaluation support.



02 认证

Certification Support

产品认证辅导及注册项目支持，协调技术沟通、资料准备与问题回复，跟进申请进度和获证后的维护事项。

Certification and registration support: technical coordination, documentation, query responses, application tracking and post-certification maintenance.



03 检测

Testing

按产品需求组织安全、性能及软件测试，提供网络信息安全、数据安全测试支持，协同实验室推进验证、整改与复测。

Safety, performance and software testing, including cybersecurity and data security, with laboratory coordination for verification, remediation and retesting.



服务覆盖 25+ 行业领域

Serving 25+ Industry Sectors

医疗器械、 IVD 、新能源、家电、照明、机械、实验室仪器、无线产品及信息安全等。

Medical devices, IVD, new energy, appliances, lighting, machinery, laboratory equipment, wireless products and information security.



我们协同全球本地资源，为您的产品提供高效的市场准入方案。

We coordinate local resources worldwide to deliver efficient market access solutions for your products.

授权代表与当地支持

Authorized Representation and Local Support

中国 + 欧盟、美国、泰国、新加坡、越南、马来西亚、印度尼西亚、香港…

China + EU, USA, Thailand, Singapore, Vietnam, Malaysia, Indonesia and Hong Kong…

衔接注册、文件留存、监管沟通及上市后维护。

Registration coordination, document retention, regulatory communication and post-market support.

我们的核心优势

Our Core Strengths

1

全球法规经验

Global Regulatory Know-how

覆盖医疗器械与 IVD 主要市场准入路径。

Coverage of major market-access pathways for medical devices and IVD.

2

实战型专家团队

Experienced Practitioners

拥有制造商、认证机构、公告机构及实验室实务经验。

Hands on experience from manufactory，Certification bodies, notified bodies and industry roles.

3

一站式交付

One-stop Delivery

从差距评估到文件、测试、注册全流程支持。

End-to-end support from gap assessment to documentation, testing and registration.

4

资源协同网络

Resource Network

联动实验室、当地代表及各区域技术伙伴。

Coordination with labs, local representatives and technical partners across regions.

重点项目类别

Key Project Categories

围绕有源、医美、 IVD 、植入及独立软件五大品类的技术特点与目标市场，提供合规、认证与检测支持。

Compliance, certification and testing support tailored to active, aesthetic, IVD, implantable devices and standalone software.



01 有源器械
Active Devices

- 监护仪 Patient Monitors
- 内窥镜系统 Endoscopy Systems
- 超声诊断设备 Ultrasound Systems

02 医美器械
Medical Aesthetics

- 射频 / 激光设备 RF & Laser Devices
- 水光注射仪 Mesotherapy Injectors
- 重组胶原产品 Recombinant Collagen

03 IVD 器械
In Vitro Diagnostic Devices

- 体外诊断设备 IVD Instruments
- 分子诊断试剂 Molecular Diagnostics
- 生化 / 免疫试剂 Chemistry & Immunoassay

04 植入器械
Implantable Devices

- 骨科螺钉与接骨板 Bone Screws & Plates
- 人工关节 Joint Replacements
- 口腔种植体 Dental Implants

05 独立软件
Standalone Software (SaMD)

- AI 影像辅助诊断软件 AI Imaging Diagnosis
- 临床决策支持软件 Clinical Decision Support
- 移动医疗 App Mobile Health Apps

合作机构与认证范围

Partners and Certification Scope

合作检测认证机构

Testing and Certification Collaborators

全球认证与注册服务范围

Global Certification & Registration Services

欧盟 CE 合规 EU CE Compliance	美国 FDA 注册 US FDA Registration	中国 NMPA 注册 China NMPA Registration	巴西 ANVISA 注册 Brazil ANVISA Registration	中国 CCC 认证 China CCC Certification
北美 UL 认证 North America UL Certification	美国 FCC 合规 US FCC Compliance	英国 UKCA 合规 UK UKCA Compliance	泰国 TISI 认证 Thailand TISI Certification	印尼 HALAL 认证 Indonesia Halal Certification

以上为可承接的认证与注册业务，具体方案以产品评估结果为准。

Services listed are indicative; the final scope depends on product assessment.

与我们讨论您的医疗产品

Discuss Your Medical Product with Us

告诉我们产品用途、目标国家和研发阶段，我们将据此讨论合规路径、验证需求与项目安排。

Tell us the products intended use, target countries and development stage of your product so we can discuss regulatory pathways, verification needs and project planning.

邮箱： contact@everbiz.de

网址： www.everbiz.com.cn / www.everbiz.de

微信联系
WeChat

WhatsApp 联系
WhatsApp

微信公众号
WeChat Official Account

中国 · 上海
Shanghai, China
上海市宝山区陆翔路 111 弄 6 号楼 705 室
Room 705, Building 6, Lane 111, Luxiang Road, Baoshan District, Shanghai

德国 · 慕尼黑
Munich, Germany
Landsberger Str.155, 80687 München, Germany

奥地利 · 萨尔茨堡
Salzburg, Austria
Rosa-Hofmann-Straße 33, 5020 Salzburg, Austria

越南 · 胡志明市
Ho Chi Minh City, Vietnam
No. 8L, Phu Lam D Residential Area, Street 32B, Binh Phu Ward, Ho Chi Minh City, Vietnam

中国 · 香港
Hong Kong, China
Room A1, 11/F Winner Building, 36 Man Yue Street, Hung Hom, Kowloon

泰国 · 曼谷
Bangkok, Thailand
No.850 Soi Lat Krabang 30/5, Lat Krabang Subdistrict, Bangkok 10520

新加坡
Singapore
133 New Bridge Road, #8-1, Chinatown Point, Singapore 059413

马来西亚 · 吉隆坡
Kuala Lumpur, Malaysia
Unit No.92A, Jalan 13/142, Taman Orkid Desa, 56000 Kuala Lumpur, Malaysia