医疗器械质量管理体系 认证证书

证书号: HXC18924YL005R0S

兹证明

深圳市信易科技有限公司

统一社会信用代码: 91440300MA5DMK0Q56

注册地址:广东省深圳市龙岗区龙岗街道南联社区瑞记路 1号 S座、T座 S座 201 办公地址:广东省深圳市龙岗区龙岗街道南联社区瑞记路 1号 S 座、T 座 S 座 201 生产/经营地址:广东省深圳市龙岗区龙岗街道南联社区瑞记路 1号 S座、T座 S座 201

医疗器械质量管理体系符合

GB/T 42061-2022/ISO 13485: 2016 标准要求

通过认证的范围为

非植入性门诊监测系统 PCBA 的加工

第一次监审

贴标处

第二次监审

贴标处

第三次监审

贴标处

证书有效期内, 获证组织须每年至少接受一次监督审核并加贴合格标志, 证书方为有效。 本证书信息可在国家认证认可监督管理委员会官方网站: www.cnca.gov.cn查询。 证书有效性以右侧二维码扫描内容为准





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初次获证日期: 2024年9月4日 北京市昌平区科技园区振兴路 28 号 2 号楼 228 室

签发日期: 2024年9月4日

有效日期: 2027年9月3日 010-57146599

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certificate No.: HXC18924YL005R0S

Awarded to

Weller Technology Co., Ltd.

Organization Code:91440300MA5DMK0Q56

Registered Add.: No.1 of Building S, 201 of Building T and Building S, Ruiji Road, Nanlian Community, Longgang Street, Longgang District, Shenzhen City, Guangdong Province Office Add.: No.1 of Building S, 201 of Building T and Building S, Ruiji Road, Nanlian Community, Longgang Street, Longgang District, Shenzhen City, Guangdong Province Production/Business Add.: No.1 of Building S, 201 of Building T and Building S, Ruiji Road, Nanlian Community, Longgang Street, Longgang District, Shenzhen City, Guangdong Province

The Medical Devices Quality Management Systems of the above Organization has been assessed and Found to be in accordance with the requirements of the standard:

GB/T 42061-2022/ISO 13485: 2016

Scope of this management Certification

Processing of PCBA for non implantable outpatient monitoring system

First S.A. Labelling Second S.A. Labelling

Third S.A.

Labelling

The certified organization must accept at least one surveillance audit annually and a qualified mark shall be attached onto the certificate, within validity period of the certificate, then the certificate can be maintained valid.

For more details of this certificate, please login CNCA's website: www.cnca.gov.cn.

For the validity of the certificate, please scan the QR codes on the right ride for accurate information.









Date of Original Issued:4 Sep. 2024 Valid from:4 Sep. 2024 Valid until:3 Sep. 2027 Room 228, Building 2, No.28 Zhenxing Road, Science Park, Changping District, Beijing