

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 117 17 Q0M 0002 R1M This is to certify the quality management systems of

ONCORE MANUFACTURING SERVICES (SUZHOU) INC.

Unified Social Credit Code 913205947628494658

Location Building 5, No. 42 Dongfu Road, Suzhou Industrial Zone, Suzhou, Jiangsu

has been assessed and registered as meeting the requirements of ISO13485: 2016<Medical device-Quality management systems - Requirements for regulatory purposes>

Scope of approval

SMT Production Processing of PCBA for Breathing Machine, Nuclear Magnetic Resonance Equipment and Sports Medical Scalpel

Signed by:

First Certification: 19 Sep. 2014
Recertification Date: 11 Jan. 2017
Expiry Date: 10 Jan. 2020
Revision Date: 08 Jan. 2018

Shanghai Ingeer Certification Assessment Co.,Ltd.

Certification and Accreditation Administration of PRC:CNCA-R-2003-117 Tel: 400-182-9001/+86 21-51114700

Web: www.icas.org.cn

Add: Room 801, HuaDing Mansion, 2368# West Zhongshan Rd.,

Xuhui District, Shanghai, China, 200235



Focus on icas WeChat platform



First Surveillance Audit Second Surveillance Audit Third Surveillance

The ownership of the certificate belongs to Shanghai Ingeer Certification Assessment Co., Ltd. The information & validation of this certificate can be checked on the CNCA website: WWW.CNCA.GOV.CN and ICAS website, or by calling ICAS's clients services Dept. The certificate is only valid when used together with related permits when appropriate. If the organization can't effectively maintain the above management system, ICAS has the right to withdraw the qualification certificate.



管理体系认证证书

认证编号: 117 17 Q0M 0002 R1M

岛扩电子(苏州)有限公司

统一社会信用代码 913205947628494658

地址 江苏省苏州市苏州工业园区东富路 42 号 5 栋

经现场评审满足 ISO13485: 2016 医疗器械质量管理体系要求

以证范围 呼吸机用、核磁共振设备用、运动医疗手术刀用 PCBA 的 SMT 生产加工



初次发证: 2014年09月19日复评发证: 2017年01月11日

有效期至: 2020年01月10日

变更日期: 2018年01月08日

上海英格尔认证有限公司

国家认监委批准号: CNCA-R-2003-117 电话: 400-182-9001/+86 21-51114700

网址: www.icas.org.cn

地址: 上海市徐汇区中山西路2368号 华鼎大厦801室 200235



关注英格尔微信平台



本证书的所有权属上海英格尔认证有限公司,证书信息及有效性可在国家认监委官方网站(www.cnca.gov.cn)上查询,也可通过登录英格尔官方网站或致电英格尔客户服务部进行查询。本证书在国家规定的各行政、资质许可范围及有效期内使用有效。获证组织必须定期接受年度监督审核并经审核合格此证书方继续有效;如获证组织未能有效维持以上管理体系,英格尔有权收回其获证资格。