Certificate CN24/00005412

The management system of



Knowles Electronics (SuZhou) Co., Ltd.

No. 20 Chunxing Road, Caohu Street, Xiangcheng Economic Development District, Suzhou, Jiangsu, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Manufacture of plastic injection parts used for non-active medical devices, active medical devices (non-implantable) and active implantable medical devices

This certificate is valid from 27 August 2024 until 26 August 2027 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 27 August 2024

Jordan U. Hell

Authorised by Jonathan Hall Global Head - Certification Services

SGS United Kingdom Ltd Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK t +44 (0)151 350-6666 - www.sgs.com







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此为证书 CN24/00005412 译本 下述组织

SGS

楼氏电子(苏州)有限公司

中国江苏苏州相城经济开发区漕湖街道春兴路 20 号

的管理体系已经过审核,并被证明符合下述要求

ISO 13485:2016 EN ISO 13485:2016

所涉及的活动范围覆盖

用于无源医疗器械,有源非植入医疗器械和有源植入医疗器械的注塑件的生产

该证书的有效期自 2024年08月27日 至 2027年08月26日 并须经过符合要求的监督审核保持有效 版本号 1. 初始注册日期 2024年08月27日

Jordhan U. Hall

签署

Jonathan Hall Global Head -Certification Services

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