

Certificate CN17/20001

The management system of

RAFI Electronics (Shanghai) Co., Ltd.

Building 4th & 8th. No. 1855, Tianchen Road, Qingpu Industrial Zone,
Shanghai, 201712, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 30 January 2019 until 29 January 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 December 2021
Issue 3. Certified since 3 January 2017

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Page 1 of 2



0005



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

RAFI Electronics (Shanghai) Co., Ltd.

ISO 13485:2016 EN ISO 13485:2016



Issue 3

Detailed scope

Design, manufacture and sales of control units and printed circuit board assemblies (PCBA) for active medical devices (non-implantable)

Additional facilities

Unit 306-308, Building B, Venture International Park, No. 2679, Hechuan Road,
Shanghai, 201103, P.R. China



0005