



KAERTECH LIMITED

Suite 1601-2, Seaview Commercial Building, 21-24 Connaught Road West
Sheung Wan, Hong Kong

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 12 August 2021 until 08 July 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 4. Certified since 09 July 2018

The audit leading to this certificate commenced on 24 May 2021
Previous issue certificate validity date was until 08 July 2021

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

Authorised by



0005

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

21HC 13485 2016 0421 M2

Page 1 of 2



KAERTECH LIMITED

ISO 13485:2016
EN ISO 13485:2016



Issue 4

Detailed scope

Manufacture of electric dental devices, active medical devices for monitoring of human physiological parameters and non-sterile orthodontic devices

Additional facilities

Site 2: Kaertech Electronics Philippines, Inc.

Building 3, EZP Compound, Laguna Technopark Annex
Binan, Laguna, Philippines



0005