



Certificate JP06/040177

The management system of

Serotec Co., Ltd.

Chitose Factory

1007-67 Izumisawa, Chitose-shi, Hokkaido,
066-0051, Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

**Design and Manufacture of in vitro diagnostic medical devices
for clinical chemistry, including enzymes, lipids/lipoproteins,
carbohydrate metabolites, non protein nitrogen compounds,
proteins and inorganic materials**

This certificate is valid from 6 April 2021 until 6 April 2024 and
remains valid subject to satisfactory surveillance audits.

Re certification audit due before 6 April 2024

Issue 9. Certified since 6 April 2006

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

Page 1 of 1



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.