

Certificate CN14/31038

SGS

The management system of

Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

No. 8, Shengchang West Road, Danyang Development Zone, Jiangsu Province, 212300, 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 08 September 2023 until 07 September 2026 and remains valid subject to satisfactory surveillance audits.

Issue 12. Certified since 08 September 2014

Jonathan M. Hall

Authorised by
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Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

ISO 13485:2016

EN ISO 13485:2016

Design, Manufacture and Distribution of Fingertip Pulse Oximeter, Wrist Pulse Oximeter, Patient Monitor, Urine Analyzer, Multi Parameters Health Examination System (including Software), Suction Machine, Oxygen Concentrator, White Blood Cell Analyzer, Blood Cell Staining Solution, Hemoglobin Microcuvette (Spectrophotometry), Biochemistry Analyzer, Fluorescence Immunoassay Analyzer, Hemoglobin Analyzer, Digital Sphygmomanometer

Design, Manufacture and Distribution of Novel Coronavirus COVID-19 IgM/IgG Test Kit (Colloidal Gold), COVID-19 Antigen Rapid Test Kit (Colloidal Gold), Influenza A&B Rapid Test Kit (Colloidal Gold) and COVID-19/Influenza A&B Antigen Rapid Test Kit (Colloidal Gold), COVID 19 Salivary Antigen Rapid Test Kit (Colloidal Gold), COVID 19 Neutralizing Antibody Rapid Test Kit (Colloidal Gold), Total Cholesterol/Uric Acid/Glucose Test Card (Dry Chemical Method), Blood Lipid and Glucose Test Card (Dry Chemical Method), Urea/Creatinine/Uric Acid Test Card (Dry Chemical Method), Alanine Aminotransferase/Hemoglobin Test Card (Dry Chemical Method), Alanine Aminotransferase/Aspartate Aminotransferase/Albumin Test Card (Dry Chemical Method)



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