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Certificate CN14/31038

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

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 and Time resolved immunofluorescence analyzer
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)

This certificate is valid from 18 January 2021 until 07 September 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 03 July 2023
Issue 8. Certified since 08 September 2014

Authorised by

UKAS MANAGEMENT SYSTEMS
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

HC SGS 13485 2016 0118

EC Certificate Full Quality Assurance System: Certificate CN19/41042

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

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

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

This certificate is valid from 01 March 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 5. Certified since 08 September 2014

Certification is based on reports numbered CN/SZX 49730

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 5

Detailed scope

Fingertip Pulse Oximeter used for home care and medical outpatient department,
Wrist Pulse Oximeter used for home care and medical outpatient department,
Patient Monitor used for vital physiological parameters
Models: AURORA 8, AURORA 10, AURORA 12, AURORA 8s, AURORA 10s, AURORA 12s,
Multi-parameters Health Examination System (including software) used for Measuring and recording Multiple physiological parameters (Models: HES-3, HES-5, HES-7)
Suction Machine(Models: 9E-A, 9E-B)
Oxygen Concentrator (Models: KSN-5, KSOC-5, KSW-5, KSOC-10)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.