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 analyzer, Hemoglobin Microcuvette (Spectrophotometry), Biochemistry analyzer, Time resolved immunofluorescence analyzer, Novel Coronavirus COVID-19 IgM/IgG Test Kits(Colloidal Gold)

This certificate is valid from 16 July 2020 until 07 September 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 03 July 2023
Issue 7. Certified since 08 September 2014

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

此为证书 CN14/31038 译本
This is an SGS translation of CN14/31038 Issue 7

下述组织

江苏康尚生物医疗科技有限公司

中国江苏省丹阳市经济开发区圣昌西路 8 号 212300

的管理体系已经过审核，并被证明符合下述要求

ISO 13485:2016
EN ISO 13485:2016

所涉及的活动范围覆盖

指夹式脉搏血氧仪、腕式脉搏血氧仪、病人监护仪、尿液分析仪、多参数健康检查系统、吸痰器、医用制氧机、白细胞分析仪、白细胞分析仪染色液、血红蛋白分析仪、血红蛋白检测试剂卡(分光光度法)、干式生化分析仪、荧光免疫分析仪、新型冠状病毒（2019-nCoV）IgM/IgG 抗体检测试剂盒(胶体金法)的设计、制造和销售

该证书的有效期自 2020-07-16 至 2023-09-07
并须经过符合要求的监督审核保持有效
持续认证需在 2023-07-03 之前执行
版本号 7. 初始注册日期 2014-09-08

签署

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 16 July 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 08 September 2014
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/SZX 49730

Authorised by

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 4

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)

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.