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

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

# 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.