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
212300 Jiangsu Province, 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 April 2020 until 19 June 2022
and remains valid subject to satisfactory surveillance audits.
Issue 3. 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

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

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 3

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.