



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MED

Tip		Введите текст для поиска...							
I.3. Certificatul CE	Denumire Certificat CE	Nr	Denumire	Model	Tara	Producatorul	Reprezentant	Ordin	Data
I.2. Declarația de conformitate CE	Declarație de conformitate CE	DM000305461	PULSOXIMETR	FINGERTIO PULSE	China	JIANGSU KONSUNG BIO MEDICAL SCIENCE AND TECHNOLOGY, LTD	M-INTER	Rg04-000078	02-04-2021

Содержит([Representant]), M-INTER) И Содержит([Denumire], PULSOXIMETR) И Содержит([Model]) /...



Declaration of Conformity

Manufacturer:

Name: Jiangsu Konsung Bio Medical Science and Technology Co.,Ltd
 Address: No.8, Shengchang West Road, Danyang Economic Development Zone, 212300, Danyang, Jiangsu, China
 Tel.: 0511-86378666 Fax.: 0511-86381308

European Representative:

Name: Shanghai International Holding Corp.GmbH (Hamburg)
 Address: Eiffestrasse 80,20537 Hamburg Germany
 Tel: 0049-40-2513175 Fax: 0049-40-255726

Product Name: Oxygen Concentrators GMDN:12873

Classification and relevant Rule of MDD: II a MDD Annex IX, rule 11

Model No: KSOC-5,KSOC-10,KSW-5,KSN-5

Product Name: Fingertip Pulse Oximeter GMDN: 17148

Classification and relevant Rule of MDD:IIa MDD Annex IX, rule 11

Model No: Sonosat series include F01LT, F02T,F02P, F03T, F03W,F04T, F04W

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the European Representative.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

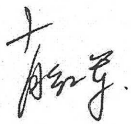
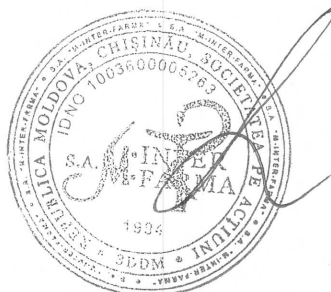
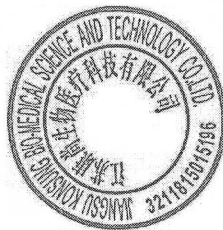
Standard:

All applicable harmonized Standard (published in the Official Journal of the European Communities)

Notified Body Name: 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

Notified Body Code: 1639
 Certificate No.: CN19/41042

Signature: Xiao Hongjun
 Position: General Manager
 Date: 2021-3-12
 Place: Zhenjiang , China

SGS

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

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6800 www.sgs.com

HC SGS 13485 2016 0118

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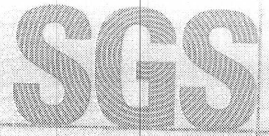
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EC Certificate Full Quality Assurance System: Certificate CN19/41042

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

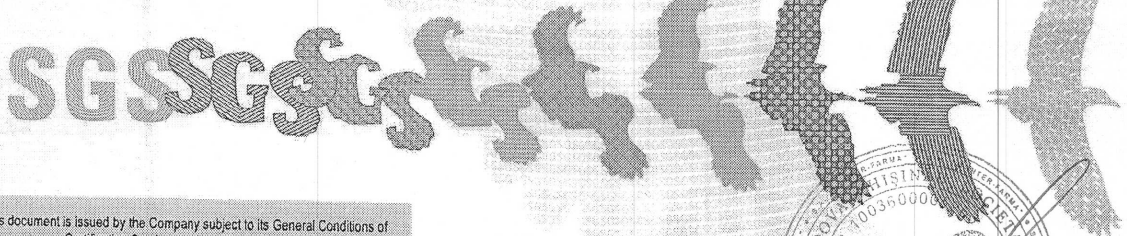
Global Medical Devices Certification Manager

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

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

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Certificate CN19/41042 continued

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

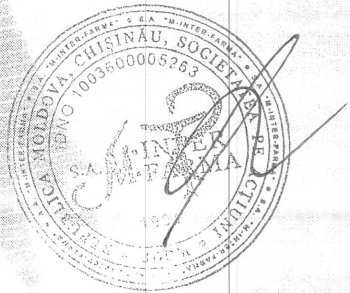
Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

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.



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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

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Global Medical Devices Certification Manager

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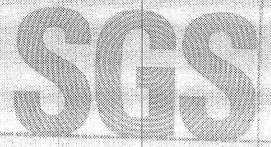
LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Certificate CN19/41042 continued

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,
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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)**

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