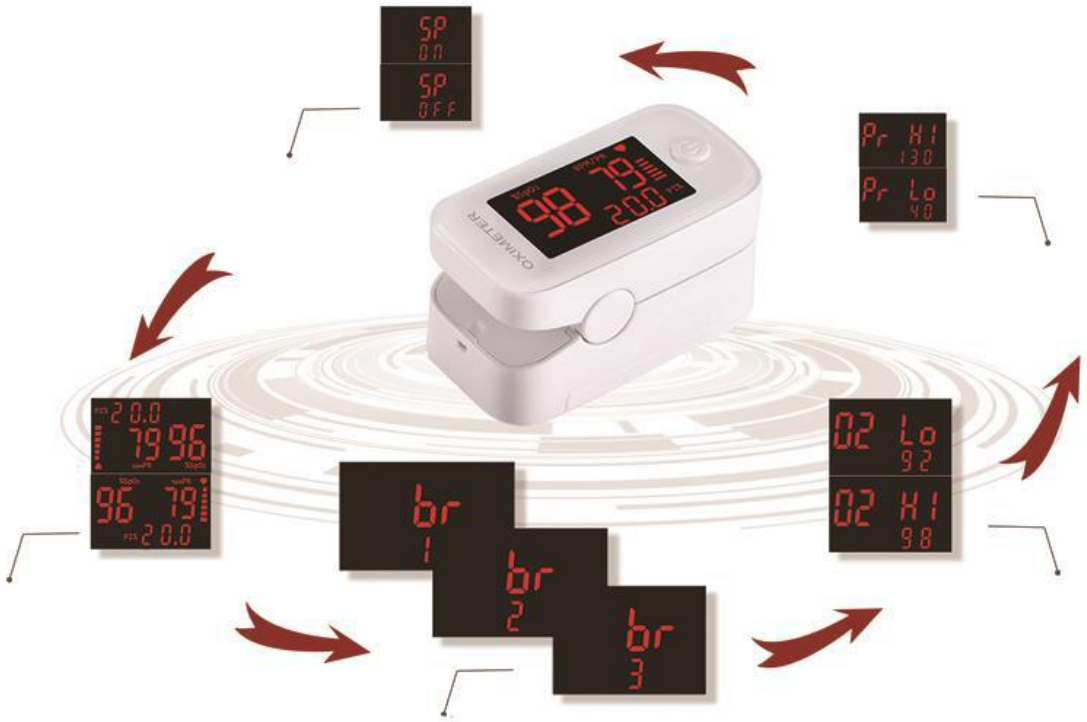
Pharma [+]

[+] aid [+] nautic [+] med [+] sport

PULSIOSSIMETRO ART.600081/F1



CARATTERISTICHE GENERALI

Design leggero e portatile
Misurazione rapida premendo un pulsante, diverse funzionalità

CARATTERISTICHE TECNICHE

SPECIFICHE
Misurazione
Precisione misurazione Spo2 70%~100% 2cifre
0%~69% non specificata
Risoluzione 1%
Campo misura Spo2 30%~99%
Precisione misurazione Spo2 in condizioni di bassa perfusione 3%con plis 0.075%
Precisione di misurazione PR 25-250 3cifre
Risoluzione 1bpm
Precisione Pr in condizioni di bassa perfusione 3bpm con plis 0.075%
Alimentazione
Specifiche batterie alcaline 2 x AAA(LR03)
Corrente 25-50mA
Modalità di operazione spot checking
Livello di protezione contro possibilità di esplosione IP022
Specifiche fisiche
Largherzza x altezza x profondità 57 x 30 x 31 mm
Peso 28g (sola macchina)
Rep. 1942317 CND Z1203020408

Rev.2020

PHARMAPIU' srl tel. fax e-mail http
65013 Città Sant'Angelo (PE) Italy – Str. Provinciale Lungofino, 187 | +39 085 9508120 | +39 085 9508930 | info@pharmapiu.com | www.pharmapiu.com

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 December 2019 until 19 June 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. 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

This is a multi-site certification.
Additional site details are listed on subsequent pages

Authorised by

Pieter Weterings
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 1

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;
Handheld Monitor used for Measuring Multiple Physiological Parameters
Models: SONOSAT-H01A, SONOSAT-H01B, SONOSAT-H01C

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

Additional facilities

Room A01, 14th floor, 1st Hall, Gaoxinqi Strategic Emerging Industrial Park, Plan 2, LiuXianYi Road, No. 67, Baoan District, Shenzhen City, Guangdong Province, 518101, P.R. China

DECLARATION OF CONFORMITY

Name: Jiangsu Konsung Bio-Medical Science and Technology Co.,Ltd

Address: No.8, ShengChang West Rd, Economy Development Zone, Danyang, Jiangsu, China

I, WangQiang, hereby declare that the below mentioned medical device—

(i) complies with all the requirements under the Act;

(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and

(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name: **Oximeter**

Specified name: **Fingertip Pulse Oximeter**

Brand/model: **konsung/SONOSAT-F01T、SONOSAT-F01W、SONOSAT-F01P、SONOSAT-F01LT、SONOSAT-F01LP、SONOSAT-F02T、SONOSAT-F02W、SONOSAT-F02P、SONOSAT-F02LT、SONOSAT-F02LW、SONOSAT-F02LP、SONOSAT-F03T、SONOSAT-F03W SONOSAT-F03P、SONOSAT-F04T、SONOSAT-F05LT 、SONOSAT-F05LW、SONOSAT-F05LP**

Manufacturer: **Jiangsu Konsung Bio-Medical Science and Technology Co.,Ltd**

Country of origin: **China**

Manufacturing site: **Danyang, Jiangsu Province**

Risk-based classification: **Class B** Classification rule:**2**

(Note: according to First Schedule on Rules of Classification of Medical Device)

Medical device registration number or any approval code:20142210627

(B) Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate:SGS

Certificate number: ISO 13485 Certificate No. 201600118M2

Issuance date:2019-04-04

Expiry date: 2020-09-07

(C) Standards Applied

Please state and list all standards applicable for the above-mentioned medical device.

I am fully responsible with all the information provided in this declaration. This declaration of conformity is

valid from …5…… (Day) …11.. (Month) ……2019……..(Year).

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Jiangsu Konsung Bio Medical Science and Technology Co., Ltd

Add: No.8, ShengChang West Rd, Danyang, Jiangsu, China

Tel: +86-511-86375968 Fax: +86-511-86371668

Authorised Signatory:

Wang Qiang/ General manager 2019-11-05
Name/Position Date

Jiangsu Konsung Bio Medical Science and Technology Co., Ltd
Add: No.8, ShengChang West Rd, Danyang, Jiangsu, China
Tel: +86-511-86375968 Fax: +86-511-86371668