

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

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Authorised Signatory:



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



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