



# Attestation of Conformity

No. ICR Polska/M4400156



**Name and address  
of Registered Manufacturer:**

Suihua Xinfeng Technology Co., Ltd.  
Building 7 (No.19, Xingsui Road) In The Hospital Of Nuojie  
Pharmaceutical Co., Ltd., Suihua City, Heilongjiang Province

**Product name:**

Non-contact infrared human body thermometer

**Product type/model:**

ZK-1026, ZK-SH1026, ZK-SH1027, ZK-SH1028, ZK-SH1029,  
ZK-SH1030

**Trade mark:**

N.A.

**This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.**

**Relevant EC Directive:**

Medical Device Directive 93/42/EEC

**Conformity assessment  
procedure:**

EC Declaration of Conformity (Annex VII of Directive  
93/42/EEC)

**Classification:**

Class I according Rule 1 of Annex IX of Directive 93/42/EEC

**Applied normative documents:**

EN 60601-1: 2006  
EN 60601-1-2: 2015

**Applied Quality  
Management System**

n/a

This AoC will remain valid only if Quality Management System Certificate remains valid.  
The assessment process has been carried out in accordance with the program PC-P-07-07.  
Evaluation has been carried out in accordance with test report made by:

- Shenzhen TCI Testing Technology Co., Ltd.

**No. of test report:**

TCI2003064978

**Issue date:**

25.03.2020

**Expiration date:**

24.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR  
Polska/2020-3125.

This Attestation applies to products having the same attributes (parameters), intended use, that have  
been evaluated and meet the requirements of the aforementioned standard.



Director: Rafał Kalinowski



Warsaw, 25. 03. 2020.

**ICR Polska Co. Ltd.**

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Shenzhen BEL Technology Co.,Ltd.

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Town, Bao'An District, Shenzhen, Guangdong, China.



# Certificate of Compliance

**Certificate Number: BEL20200000101899**

**Applicant** : Shenzhen Wanlianxin Electronic Co., Ltd.  
**Address** : Xingye Huating, 48 District, Haihua community, Xin'an street, Bao'an District, Shenzhen 202  
**Manufacturer** : Shenzhen Wanlianxin Electronic Co., Ltd.  
**Address** : Xingye Huating, 48 District, Haihua community, Xin'an street, Bao'an District, Shenzhen 202  
**Product** : FINGERTIP PULSE OXIMETER  
**M/N** : WLX501  
WLX502, WLX503, WLX504, WLX505  
WLX506, WLX507, WLX508, WLX509  
**Test Standard** : EN 60601-1:2006+A12:2014  
EN 60601-1-2:2015

The EUT described above has been tested by us with the listed standards and found in compliance with the council Medical products general directive 2007/47/EC. It is possible to use CE marking to demonstrate the compliance with this EMC Directive.

It is only valid in connection with the test report number: BEL20200000101899



Manager

May. 24, 2020

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole product and relevant Directives have to be observed.

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