



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.

Add: 3rd Floor, Xingfu Building, Tongfuyu Industrial Zone, Shiyan
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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