

Attestation of Conformity

No. ICR Polska/M4400156



Name and address Suihua Xinfeng Technology Co., Ltd.

of Registered Manufacturer: 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

ZK-1026, ZK-SH1026, ZK-SH1027, ZK-SH1028, ZK-SH1029, Product type/model:

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.

Medical Device Directive 93/42/EEC Relevant EC Directive:

Conformity assessment EC Declaration of Conformity (Annex VII of Directive

procedure: 93/42/EEC)

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

EN 60601-1: 2006 **Applied normative documents:** EN 60601-1-2: 2015

Applied Quality

Management System

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:

n/a

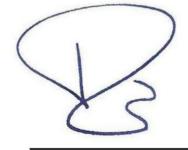
Shenzhen TCI Testing Technology Co., Ltd.

No. of test report: TCI2003064978 Issue date: 25.03.2020 24.03.2025 **Expiration date:**

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.



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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: BEL2020000101899

Applicant

: Shenzhen Wanlianxin Electronic Co., Ltd.

Address

: Xingye Huating, 48 District, Haihua community, Xin'an street, Bao'an District, Shenzhen

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Manufacturer

Shenzhen Wanlianxin Electronic Co., Ltd.

Address

Xingye Huating, 48 District, Haihua community, Xin'an street, Bao'an District, Shenzhen

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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: BEL2020000101899

CE



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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