

CONFORMITY CERTIFICATE

No. 211299057

Manufacturer: **BIORS LLC**
455-3 Ivana Babushkina street
117292 Moscow
Russia

Product: **Hardware-software complex Bioscanner Wellness**

Type: **Bioscanner Wellness**

Specifications: **the product specification is given on the other side of the certificate**

This conformity certificate confirms the conformity of the product with essential safety requirements of the following EC/EU New Approach Directives as amended:

2014/30/EU Electromagnetic compatibility

Harmonized standards used for conformity assessment:

EN 55014-1:2017
EN 55014-1:2017/A11:2020
EN 55014-2:1997
EN 55014-2:1997/AC:1997
EN 55014-2:1997/A1:2001
EN 55014-2:1997/A2:2008

The certificate has been issued on the basis of the tests of the product type sample.
The results are recorded in the Conformity assessment report No. 210500045 dated 24.02.2021



mark can be used only in the case of conformity assessment according to all relevant EC/EU Directives.

This certificate is issued under the following conditions:

1. The certificate applies to the product type specified in the above mentioned Conformity Assessment report.
2. The production process/factory production control is not covered by this certificate.
3. The certificate does not imply that the certification body has performed any surveillance or control of the production process.
4. The manufacturer shall ensure the conformity of subsequent production items with the certified type.
5. Changes that may have an impact on maintaining conformity with the certification requirements may require confirmation of the validity of the certificate by demonstrating compliance with the conditions under which the certificate was issued or by conducting an additional evaluation.
6. The holder of this certificate must keep the conditions specified in the General Rules for Product Certification, which are freely available at www.tsu.eu.

Issue date: 25.02.2021
Expiry date: 24.02.2024
Issue: 1



Ján BARANČÍK

Deputy of Head of Product Certification Body

TSU Piešťany, š.p. is Notified Body No. 1299

124255

The product specification

Photo of «Bioscanner Wellness»



Main parameters and characteristics of «Bioscanner Wellness»:

Parameter name	Value
Control system	Computer program-controlled device
Interface of connection and data transfer	USB port
Voltage supply from PC USB port, V	5
Nominal current consumption, A, not more than	0.8
Data transfer rate, Mbit/s	2.1 max
Operation mode setup time, min, not more than	6
Weight, kg, not more than	4
Overall device dimensions (depth, width, height), mm	165 x 202 x 46
Pulseoximeter	
Overall sensor dimensions, not more than, mm	65 x 40 x 30
Measuring range of the blood oxygen saturation, %	70–100
Sensor wavelengths (optical and infrared wavelength band), nm	660, 940
Flux power, mW, not more than	0.8
Bioimpedance analyzer	
The measuring method	tetrapolar
Amplitude of bioimpedance probe voltage, V, not more than	+ 5/- 5
Measuring range of active resistance, Ohm	70–800
Measuring range of reactive resistance, Ohm	30–90
Probe frequency range, kHz	10–100
Electrosomatograph	
Number of registered leads	22
Voltage at $R_h = 100 \text{ k}\Omega$, V	0.64
Short-circuit current, μA , not more than	12.8
Electrocardiograph	
10 registered leads	RA, LA, RL, LL, V1...V6
Input voltage range, mV	0.03–10.00
Range of sensitivity (for entire aperture), mV	± 200
Input impedance, for all inputs except R, Mohm, not less than	5
Common-mode rejection ratio, dB, not less than	115
Measurement error of the voltage, mV, not more than	$\pm 15 \%$
Direct current in ECG measurement circuit, μA , not more than	0.1
A/D converting, bit	24
Self-noise level, mV, not more than	0.007

