Declaration of conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product name, model: Monitoring Device For Non-Vital Physiological Parameters **SensitivE Audit®**
Model 555 **# R500A106US**

Manufacturer, address:
ALFA-MED LLC
34 Shabolovka street, Moscow, 115419, Russia
Web: www.alfa-med.ru/en
Phone / fax: +7 (495) 601-91-63, e-mail: otvetalfamed@gmail.com

The object of the declaration described above is in conformity with the relevant Union harmonisation legislations:

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast).

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Used standards: EN 55011:2016/A1:2017, EN 60601-1-2:2016, EN 61000-4-2:2009, EN 61000-4-3:2006/A1:2008/A2:2010, EN 61000-4-4:2013, EN 61000-4-5:2014, EN 61000-4-6:2014, EN 61000-4-8:2010, EN 60950-1: 2006/A11: 2009/A1: 2010/A12: 2011/A2: 2013

Notified body: International Center for Quality Certification - ICQC LLC. Notified Body No. 2549.
EU-type examination of apparatus carried out according to module B (Part A Annex III to Directive 2014/30/EU) and issued EU-Type Examination Certificate No. 3-201-287/2018 dated September 28, 2018

Test report references: No. LEITC-TR-18-132(01) dated 18 September 2018 (Latvian Electronic Equipment Testing Center Ltd)
No. 1311834506/45078/TR/18 dated 26 September 2018 (TÜV Nord Baltik Ltd)

I, the undersigned, representing the manufacturer's, declare in sole responsibility, that the product specified above, to which this declaration relates, conforms to the above mentioned Directives and Standards.

Andrey Kiselev, General Director

This product carries the CE Mark, which was first applied in 2018.

Date and place of issue: November 15, 2018
Moscow, Russia