



RUSSIA

**Monitor Ltd**

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## **Research & Production Company «Monitor» Limited.**

Is presented by the Authorized Representative in EC  
“Labtech Ltd.”

Address: 4031 Debrecen, Vag Street, 4, Hungary

### **DECLARATION OF CONFORMITY**

**The undersigned, Yury Popov, director of Research & Production Company  
“Monitor” Limited,**

**Address: 104a Krasnokursantskaya Street, Rostov-on-Don, Russia  
hereby declares that medical device**

#### **SPIROMETER SMP 21/01 RD**

meets all requirements of Council Directives 93/42/EEC (MDD) and 2011/65/EC (RoHS).

**MDD classification:** IIa (Annex IX)

**Standards Applied:** IEC 60601-1:2012  
IEC 60601-1-2:2014  
EN 62304:2006+A1:2015  
EN ISO 26782:2009  
EN ISO 23747:2015

This Declaration of Conformity is based on European Medical Device Directive 93/42/EEC Annex II and European Directive 2011/65/EU (RoHS).

**Certificate No.:** CE 543428 dated 18 Feb 2019

**Certificate No.:** MD 543429 dated 05 Feb 2019

**Notified Body:** The British Standards Institution  
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands,  
Notified Body Number 2797

**Valid until:** December 31, 2020

Signature

Date: January 14, 2020

(Yury Popov)