



RUSSIA

**Monitor Ltd**

104a, Krasnokursantskaya St., Rostov-on-Don, 344068  
Tel/Fax +(7863)2436111,2436377,2310401 (02,03,11)  
E-mail: qm@monitor-ltd.ru

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

Is presented by the Authorized Representative in EC  
CMC Medical Devices & Drugs S.L.  
Address: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

### **DECLARATION OF CONFORMITY**

**The undersigned, Yury Popov, general director of Research & Production Company “Monitor” Limited,  
Address: 104a Krasnokursantskaya Street, Rostov-on-Don, Russia  
hereby declares that medical device**

#### **DIAGNOSTIC SYSTEM FOR PERSONAL PATIENT MONITORING SPDM 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  
IEC 60601-2-25:2011  
IEC 60601-2-47:2012  
EN 62304:2006+A1:2015

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 03 Sept 2020

**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:** September 02, 2021

Signature

(Yury Popov)

Date: September 04, 2020