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Declaration of conformity

We — **OOO Petr Telegin**
Gagarin avenue, 37, build P1,
Russia, 603009, Nizhny Novgorod

Authorized representative — **BPLab GmbH**
Berliner Str. 95
65824 Schwalbach am Taunus
Germany

declare on our own responsibility that the medical device

24-hour blood pressure monitoring system BPLab®
Variant BPLab Standard serial numbers from XXXXXXXX to XXXXXXXX
Class IIa, rule 10

meets all the provisions of the Directives 93/42/EEC which are applied to it.

Applied standards:

EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices - Information supplied by the manufacturer of medical devices

EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

IEC 80601-2-30:2009 Medical electrical equipment. Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

ISO 81060-2:2013 Non-invasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type.

Notified body: BSI
Kitemark Court, Davy Avenue, Knowhill,
Milton Keynes MK5 8PP, United Kingdom
ID number 0086

Conformity assessment procedure: Annex V of the Directive 93/42/EEC.

Certificate Number: CE 576857
Start of CE-Marking: 20.08.2010

Nizhny Novgorod
Place, date:

Signature

Declaration of conformity rev. 28.08.2017