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EC DECLARATION OF CONFORMITY

issued in accordance with EC Directive 93/42/EEC relating to Medical Devices

Manufacturer: **BIOPROMIN Ltd., 50 Khalturina str., 61038 Kharkiv, Ukraine**

EU Representative: **ONKOCET Ltd., 4 Kutuzovova str., 902 01 Pezinok, Slovak Republic**

Product name: **Automatic Noninvasive Express Screening Analyzer ANESA®.**

Product description: "Automatic noninvasive express screening analyzer ANESA®", device for ex vivo automatic noninvasive determination of different parameters of the state of human body systems; models: ANESA-L/2007, ANESA-L/2007w, ANESA-L/2012, ANESA-L/2012w, ANESA-T/2009, ANESA-T/2011.

Applied directives: MD Directive 93/42/EEC

Conformity assessment route: Annex V. (product quality assurance)

Applied harmonized standards: Council Directive 93/42/EEC, EN ISO 13485:2012, MEDDEV 2.12 / 1 - rev. 8, EN 60601-1:2006/AC:2010, EN 60601-1-2:2007/AC:2010, EN ISO 14971:2012 EN 62304:2006/AC:2008, IEC 60601-1 3rd ed. 2005-12

Number, date of issue of CE certificate: **No.13 0252 QS/NB, March 26th 2013**

"MANUFACTURER" herewith declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The device – ANESA® Analyzer is safe under prescribed and reasonably foreseeable conditions of storage and use.

"MANUFACTURER" has implemented measures assuring that the ANESA® Analyzer of the above mentioned type is safe and fulfills the essential requirements of the 93/42/EEC Directive.

"MANUFACTURER" has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Date of issue: **March 26th 2013**

Director
Sydora Volodymyr