



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 13 0252 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIa

Automatic Noninvasive Express Screening Analyzer ANESA

Models: ANESA-L/2007, ANESA-L/2007w, ANESA-L/2012, ANESA-L/2012w, ANESA-T/2009, ANESA-T/2011

manufactured by company
BIOPROMIN Ltd.
50 Khalturina str., 61038 Kharkiv, Ukraine

applied by company, authorized representative:
ONKOCET Ltd., Kutuzovova 4, 902 01 Pezinok, Slovakia

are manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.2., of the Directive 93/42/EEC.

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3, and 4, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601734/2013, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

- 1. It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
- 2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 25th March 2018 at the latest.*
- 3. The Certificate validity is conditioned by positive results of surveillance audits.*
- 4. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:*



Issued in Zlín, on 26th March 2013



RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023