



Products Certification Body
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

CERTIFICATE

No. 12 0494 T/ITC

confirms that the product – in vitro diagnostic medical device according to the Directive 98/79/EC as amended, which is implemented by the Czech Government Order No. 453/2004 (Collection of Laws), model

LUCIA Cytogenetics

Image Analysis System for Cytogenetics Applications

manufactured by company

Laboratory Imaging, spol. s r.o.

Na Pasece 201/3, Praha 6 - Sedlec, 160 00 Praha 6, Czech Republic

complies with the applicable essential requirements of the European Parliament and of the Council Directive 98/79/EC on in vitro diagnostic medical devices as amended.

Referring to the intended use, the ITC Products Certification Body has conducted with successful results the type-examination of the certified product according to the relevant parts of the above mentioned Directive and appropriate harmonized European standards.

The detailed product description, documents, assessment procedures and evaluations of the examination are presented in the Final Report No. 313600306/2012, which is enclosed to this certificate.

Condition of this Certificate use and related information:

1. *It applies only to the above referenced models of the medical devices.*
2. *It does not imply that the ITC has performed any surveillance or control of their manufacture.*
3. *The manufacturer is obligated to assure conformity of all in vitro diagnostic medical devices of the respective model to type assessed by the mean of this Certificate.*
4. *The Certificate remains valid until the manufacturing conditions, the quality system or relevant legislation are changed but until the **30th June 2015** at the latest.*
5. *After fulfilling of the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking according to this example:*

CE



Issued in Zlín, on 22nd June 2012

RNDr. Radomír Čevelík
General Director