DECLARATION OF CONFORMITY

Based on the Directive 98/79/EC of the European parliament and the Council, which specifies technical demands for in vitro diagnostic medical devices

Producer:
Laboratory Imaging spol. s r.o.
Na Pasece 201/3, Praha 6 - Sedlec, 160 00 Praha 6.
IČ: 14890925 , DIČ: CZ 14890925

Declares that the following product:

LUCIA Cytogenetics

Image Analysis System for Cytogenetics Applications

Intended for:

Examination of cytogenetical tests for research and clinical puroposes

Medical devices classification:

In vitro diagnostic medical device (IVD), group A

complies all the requirements in accordance with the Directive 98/79/EC and therefore is safe for its intended purpose. The producer has developed his own quality management and has accepted all measures in order to provide product conformity of the marketed medical device with its technical documentation and requirements related to this device.

Following technical regulations, harmonised czech technical standards, documentation and notices were used to establish the conformity of this product:

Directive 98/79/EC	**In vitro diagnostic medical devices**
EN ISO 14971	**Application of risk management to medical devices**
EN 13612	**Performance evaluation of in vitro diagnostic medical devices**

The assessment of product's basic features has been executed according to the Appendix no. 1 of the Directive 98/79/EC. Conformity with the requirements related to this product has been ensured by Appendix no. 3 except article 6 of the Directive 98/79/EC.

In Prague
5. 7. 2012

Ing. Josef Mikeš, Ph.D.
MANAGING DIRECTOR

Laboratory Imaging, spol. s r.o.
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160 00 Praha 6
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