ITC

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

CERTIFICATE

No. 10 0095 T/ITC

confirms that the product - in vitro diagnostic medical device - according to the Directive 98/79/EC:

SCOUT Semi-auto Urine Analyzer

Model: RUA-100

manufactured by company

Jinan Kinghawk Technology Co., Ltd.
No.205, E South Building, Environmental Protection Technology Park, Jinan, Shandong, China

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. 313600207C/2010, which is enclosed to this certificate.

This Certificate is issued under the following conditions:

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 **31st January 2013** 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 Zlin, on 28th January 2010

RNDr. Radomír Čevelík
General Director