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

EC CERTIFICATE

No. 14 0642 QS/NB

Issued in compliance with the Directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on in vitro diagnostic medical devices as amended, which is implemented by the Czech Government Order No. 453/2004 (Collection of Laws). This certifies that the product – in vitro diagnostic medical device according to Annex II, List A of the Directive 98/79/EC

Anti-HIV 1/2 Rapid Test Kit for Detection HIV 1/2 Antibodies in Human serum or plasma
(models: Anti-HIV 1/2 Strip Test, Anti-HIV 1/2 Cassette Test)
Trade names: Laboquick, Certain, Surelab

manufactured by the company

Köroğlu Medikal Tıbbi Malz. Kozmetik Ithalat İhracat Sanayi ve Ticaret Ltd. Şti.
1776/23 Sok. No: 4/A Mevlana Mah. Bornova, Izmir, 35050 Turkey

is manufactured under conditions fulfilling the quality system requirements of Annex IV, Section 3.2 of the Directive 98/79/EC.

The Notified Body No. 1023 has performed an audit of the above product quality system. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 3.3 and 5, of the Directive 98/79/EC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 813600359/2014, 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 in vitro diagnostic 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 **9th November 2019** 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 in vitro diagnostic medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

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

Issued in Zlín, on 10th November 2014