



Notified Body No.1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlin, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC Design-Examination Certificate

## No. 14 0065 CN/NB

issued in compliance with Council Directive 98/79/EC on *in vitro* diagnostic medical devices as amended, the requirements of which are implemented by the Czech Government Order No. 453/2004 Collection of laws, for the products

**Ovulation Test**, brand names: Laboquick, Surelab, Certain, Ovula

**Menopause Test**, brand names: Laboquick, Surelab, Certain, Ovula

**Fecal Occult Blood Test**, brand names: Laboquick, Surelab, Certain, Ovula

manufactured by company

**Köroğlu Medikal Tıbbi Malz. Kozmetik İthalat İhracat Sanayi ve Ticaret Ltd. Şti**

**1776/23 Sok. No:4/A Mevlana Mah. Bornova, Izmir 35050, Turkey**

The Notified Body No. 1023 has conducted the Design examination of the above products and certifies that the requirements of Annex III, article 6 of the aforementioned directive have been met. The products description and details on the examination procedure are presented in the Final Report No. 813600331/2014, which is enclosed to this Certificate.

The Certificate remains valid until any significant change to the approved design of the above mentioned products is made but until **16<sup>th</sup> February 2019** at the latest.

*Condition of this Certificate use and related information:*

1. *It applies only to the design of the above referenced models of the *in vitro* diagnostic medical devices.*
2. *The manufacturer is obligated to assure that all *in vitro* diagnostic medical devices of the respective models conform to the type whose design has been approved by this Certificate.*
3. *After fulfilling the relevant EU legislation, 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:*

**CE**  
**1023**

Issued in Zlin, on 17<sup>th</sup> February 2014



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