**NOTIFIED BODY No. 1023**
**Institute for Testing and Certification, Inc., Zlín, Czech Republic**

# EC Design-Examination Certificate
## No. 07 0574 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 product

## Pregnancy Test
**Model: G-Test Premium 2 (Midstream)**

introduced into the market by company

## IVT Imuno, s.r.o.
**Pavlovická 12/59, 779 00 Olomouc, Česká republika**
**Company Reg. No.: 25863924**

The Notified Body No. 1023 has conducted the Design examination of the above product and certifies that the requirements of Annex III, article 6 of the aforementioned directive have been met. The product description and details on the examination procedure are presented in the Final Report No. 813600033/2007, which is an integral part of this Certificate.

The Certificate remains valid until any significant change to the approved design of the above-mentioned product is made but until 9th October 2012 **at the latest**.

*This Certificate is issued under the following conditions:*

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 Zlín, on 10th October 2007

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

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