

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

## **EC Design-Examination Certificate** No. 07 0576 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

## IVD for self-testing - Ovulation Test

Model: Your Days

introduced into the market by company

IVT Imuno, s.r.o.

Pavlovická 12/59, 779 00 Olomouc, Czech Republic

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. 813600035/2007, which is an integral part of this Certificate.

The Certificate remains valid until any significant change to the approved design of the abovementioned 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.
- 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.
- 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:

(E<sub>1023</sub>

Issued in Zlín, on 10th September 2007

RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023