



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

# EC Design-Examination Certificate

## No. 11 0276 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

### Pregnancy Test

**Model: Verto 10**

introduced into the market by company

### IVT Imuno, s.r.o.

**Pavlovická 12/59, 772 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. 813600138/2011, 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 **6<sup>th</sup> April 2016 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 7<sup>th</sup> April 2011



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