



NOTIFIED BODY No. 1023
Institut pro testování a certifikaci, a.s., Zlín, Czech Republic

EC Design-Examination Certificate

No. 07 0318 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 – *in vitro* diagnostic medical device for self - testing

Fecal Occult Blood Test

Cassette Test for Detection of Human Haemoglobin in Stool

manufactured by

IVT Imuno, s.r.o.

Pavlovická 12/59, 779 00 Olomouc, Czech Republic
Company Registration 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. 813600031/2007, which is an integral part of this Certificate.

The Certificate remains valid until any significant change to the examined design is made but until 7th June 2012 at the latest.

This Certificate is issued under following conditions:

- 1. It applies only to the above referenced models of the *in vitro* diagnostic medical devices.*
- 2. The manufacturer is obligated to assure that all medical devices of the respective models conform to design examined by this Certificate.*
- 3. The manufacturer shall affix to each product of the examined design the conformity mark CE followed by number of Notified Body according to an example:*

CE
1023

Issued in Zlín, on 8th June 2007



Mr. Pavel Voj
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023