



CERTIFICATION BODY
Institute for Testing and Certification, Inc., Zlín, Czech Republic

CERTIFICATE

No. 07 0131 V/ITC

issued in compliance with Council Directive 98/79/EC (IVD) as amended, which is implemented by the Czech Government Order No. 453/2004 Coll., certifies that the products – in vitro diagnostic medical devices for professional use, models

Pregny-Scan hCG Card Test
Pregny-Scan hCG Dipstick Test

manufactured by company

Bhat Bio-Tech India (P) Ltd.

11-A, 4th Cross, Veerasandra Industrial Area, Electronics City, Bangalore, 560 100
Karnataka, India

Tax registration id.: 29660071538

fulfil the essential requirements specified in the Annex I of the Directive 98/79/EC relating to it, taking into account the product's intended use.

The Institute for Testing and Certification has examined the above-mentioned product quality system according to the Directive 98/79/EC. The detailed product descriptions, documents, assessment procedures and evaluation of the examination are presented in the ITC's Final Report No. 813600024/2007 which is part of the Certificate.

This Certificate is issued under following conditions:

1. It applies only to the full quality assurance system maintained of above referenced models of in vitro medical devices.
2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **31st March 2010** at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. The manufacturer shall affix to each medical device of this type the conformity CE marking according to an example:



Issued in Zlín, on 20th March 2007



RNDr. Radomír Čevelík
Director general