



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

# EC CERTIFICATE

No. 07 0129 QS/NB

issued in compliance with Council Directive 98/79/EC (IVD) as amended, which is implemented by the Czech Government Order No. 453/2004 (Collection of Laws) certifies that the products – in vitro diagnostic medical devices according to Annex II, List A of the IVD Directive, models

**Hepa-Scan HBsAg card**  
**Pareekshak HIV-1/2 Spot Test**  
**Pareekshak HIV-1/2 Triline Card Test**

manufacturer

**Bhat Bio-Tech India (P) Ltd.**

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

Tax registration id.: 29660071538

are manufactured under conditions fulfilling the quality system requirements of Annex IV, Section 3.2. of the Directive 98/79/EC.

The Notified Body No. 1023 has performed an audit of the above products quality system. The quality system has been assessed, approved and is a subject of the continuous surveillance according to Annex IV, Sections 3.3. and 5. of the Directive 98/79/EC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the 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 and it does not substitute the design or type-examination or batch verification procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 19<sup>th</sup> March 2012 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *The manufacturer shall affix to each in vitro medical device of the above referenced type the conformity CE marking followed by number of Notified Body according to an example:*

**CE** 1023

Issued in Zlín, on 20<sup>th</sup> March 2007



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