Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 0430 QS/NB

Issued in compliance with the Directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on in vitro diagnostic medical devices as amended, which is implemented by the Czech Government Order No. 453/2004 (Collection of Laws). This certifies that the products – in vitro diagnostic medical devices according to Annex II, List A of the Directive 98/79/EC

Aidscan HIV-1/2 Trispot Test, Pareekshak HIV-1/2 ELISA Test, Hepa-Scan HCV Card Test, Hepa-Scan HCV ELISA Test, Hepa-Scan HBsAb Card Test, Hepa-Scan HBsAg ELISA Test, Bhat Bio-Scan Anti-A (IgM) Test, Bhat Bio-Scan Anti-B (IgM) Test, Bhat Bio-Scan Anti-D (IgM/IgG/IgM+IgG) Test, Bhat Bio-Scan Anti-AB (IgM) Test, Bhat Bio-Scan Combipack Anti ABD Test

manufactured by the company

BHAT BIO-TECH INDIA (P) LTD.
11-A, IV Cross, Veerasandra Indl. Area, Eletronics City, Bangalore-560 100, India

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 subject to continuous surveillance according to Annex IV, Section 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. 813600131/2011, which is enclosed to this certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **18th May 2016** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each in vitro diagnostic 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 19th May 2011

INSTITUTE FOR TESTING AND CERTIFICATION * 1023 * NOTIFIED BODY

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