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

EC Design-Examination Certificate

No. 11 0431 CN/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), 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

fulfil the essential requirements specified in the Annex I of the Directive 98/79/EC relating to them, taking into account the products intended use.

The Notified Body No. 1023 has executed the EC design-examination of the above-mentioned products according to the Annex IV, paragraph 4, of the Directive 98/79/EC. The detailed products descriptions, documents, assessment procedures and evaluation of the examination 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 design of the above referenced models of the medical devices.*
2. *It does not imply that the Notified Body has performed any surveillance or control of their manufacture.*
3. *The manufacturer is obligated to assure that all medical devices of the respective models conform to the type whose design has been approved by this Certificate.*
4. *The Certificate remains valid until the approved design is changed but until the **18th May 2016** at the latest.*
5. *After receiving of the complementary EC Certificate, confirming the manufacturer's quality system approval by the Notified Body No. 1023, and 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 19th May 2011

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

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