



CERTIFICATION BODY

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

CERTIFICATE

No. 07 0130 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 product – in vitro diagnostic medical device for professional use, model

Maleriscan – Malaria – P.f/P.v. 3 line Antigen 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

fulfils 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



m. Pavel Voj
RNDr. Radomír Čevelík
Director general