ITC®

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

EC CERTIFICATE

No. 10 0799 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:

HBsAg EIA Test Kit

HCV Anitibody EIA Test Kit

HIV 1/2/O Antibody EIA Test Kit

manufactured by the company

ACON Laboratories, Inc.

#10125 Mesa Rim Road, San Diego, CA 92121 ,USA

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. 813600108/2010, 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 22nd September 2015 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 Zlin, on 23rd September 2010

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