



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

EC CERTIFICATE

No. 09 0781 QS/NB

issued in compliance with Council Directive 98/79/EEC as amended, the requirements of which are implemented by the Czech Government Order No. 453/2004 Collection of laws, certifies that the Annex II list B products

Chlamydia trachomatis PCR diagnostic kit
Chlamydia trachomatis, Real-Time PCR diagnostic kit
GeneProof Cytomegalovirus (CMV) PCR kit

manufacturer

GeneProof, a. s.
Viniční 235, 615 00 Brno, Czech Republic

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 full quality assurance system. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 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. 343600489/2009.

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 **29th September 2013** 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**



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

Issued in Zlín, on 9th November 2009