



Products Certification Body
Institute for Testing and Certification, Inc. (ITC), Zlín, Czech Republic

CERTIFICATE

No. 07 0568 V/ITC

confirms that the product – in vitro diagnostic medical device according to the Directive 98/79/EC, model

Micropipettors

Types: P2, P10, P20, P100, P200, P1000, P5000, P10mL, U2, U10, U20, U100, U200, U1000, U5000, U10mL, H2, H10, H20, H100, H200, H1000, H5000, H10mL, G2, G5, G10, G20, G25, G50, G100, G200, G5000, G10mL

manufactured by company

Zhejiang Hua Wei Science Instrument Co., Ltd.

237 Zangyang Road Linhai, Zhejiang, People's Republic of China

complies with the applicable essential requirements of the European Parliament and of the Council Directive 98/79/EC on in vitro diagnostic medical devices as amended.

Referring to the intended use, the ITC Products Certification Body has conducted with successful results the type-examination of the certified product according to relevant parts of the above mentioned Directive and appropriate harmonized European standards.

Based on the audit of the quality management system implemented by the manufacturer, the ITC Products Certification Body confirms a manufacturer's ability to keep permanently the requested safety and quality level.

The more detailed product description, documents, assessment procedures and evaluations of the type-examination and of the management system audit are presented in the Final Report No. 313600096/2007, which is enclosed to this certificate.

This Certificate is issued under following conditions:

- 1. It applies only to the above referenced model of the in vitro diagnostic medical devices.*
- 2. The manufacturer is obligated to assure conformity of all in vitro diagnostic medical devices of the respective model to type assessed by the mean of this Certificate.*
- 3. The Certificate validity is conditioned by positive results of periodic 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 model, the CE-marking according to the following example:*



Ing. Pavel Vaněk
Head of the Certification Body

Issued in Zlín, on 8th October 2018