



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Products Certification Body

CERTIFICATE

No. 2013-IVD-018

confirms that the technical documentation of in vitro diagnostic medical devices not covered by Annex II and devices not for performance evaluation and not being the devices for self-testing is complete and complies with the requirements of Annex III.3 of the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, which is implemented by the Slovak Government Decree No. 569/2001 Coll. as amended:

Product Name: H. pylori Rapid Test,
Dengue Rapid Test,
Malaria P.f. / Pan Rapid Test,
Syphilis Rapid Test

Product Type: HCV Hepatitis C Virus Rapid Test
HIV 1/2 Human Immunodeficiency Virus Rapid Test
H. pylori Rapid Test (Strip-Code: IHP-301, Cassette-Code: IHP-302)
Dengue Rapid Test (Strip-Code: IDN-301, Cassette-Code: IDN-302)
Malaria P.f. / Pan Rapid Test (Cassette-Code: IMA-P402)
Syphilis Rapid Test (Strip-Code: ISY-401, Cassette-Code: ISY-402)
HCV Hepatitis C Virus Rapid Test (Strip-Code: ISY-801, Cassette-Code: ISY-802)
HIV 1/2 Human Immunodeficiency Virus Rapid Test
(Strip-Code: ISY-901, Cassette-Code: ISY-902)

Manufacturer: Tianjin YIYE Biotechnology Co., Ltd.
No.024, Room 1905. Private Economy Growth Base Creative Center of
Bin Hai, TianJin City.

A detailed description of the products, documentation and evaluation procedures is listed in the Final Protocol No. 340021/2013.

This certificate is issued under the following conditions:

It applies only to the above models of in vitro diagnostic medical devices. The Certificate remains valid unless changes in technology, quality system or the regulations invalidate it or at most until November 24th, 2018. After meeting the requirements of relevant EU legislation, the manufacturer must identify every in vitro diagnostic medical device of the above models with the CE Mark.



In Bratislava, on November 25th, 2013

Dr. Katarina Srdošová
Head of Products Certification Body