3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC DESIGN-EXAMINATION CERTIFICATE

No. 2018-IVD/DE-005

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, the requirements of which are implemented by the Slovak Government Order No. 569/2001 Coll. as amended, certifies that in vitro diagnostic medical device according to Annex II, List A,

Artron One Step Rapid Diagnostic Test:
Hepatitis C Virus (HCV) Antibody Test (Strip A02-06-213, Cassette A02-06-222)
Hepatitis B Virus Surface Antigen (HBsAg) Test (Strip A02-01-213, Cassette A02-01-222)
Human Immunodeficiency Virus 1/2 (HIV 1/2) Antibody Test (Strip A02-07-213, Cassette A02-07-222)
HIV, HBsAg & HCV Combo Test (Cassette A02-20-222)

manufactured by company

Artron Laboratories Inc.
3938 North Fraser Way, Burnaby, British Columbia, V5J 5H6, Canada

conforms with the relevant provisions of Annex IV.4 of the Directive 98/79/EC on in vitro diagnostic medical devices as transposed into national legislation. The devices fulfill the essential requirements specified in Annex I of the Directive 98/79/EC taking into account intended use of the devices.

The Notified Body No. 2265 has performed design-examination of the devices and certifies that the requirements of Annex IV.4 of the Directive 98/79/EC have been met. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocol No. 320051/2018.

This certificate is issued under the following conditions:

It applies only to the design of the above referenced models of the in vitro diagnostic medical devices and it does not imply the Notified Body executed any surveillance or control of its manufacture. The manufacturer is obligated to assure that all in vitro diagnostic medical devices of the respective models conform to the type whose design has been approved by this certificate. The certificate remains valid until the approved design is changed but till August 25th, 2023 at the latest. This EC design-examination certificate is complementary to an EC Certificate, approving the manufacturer's quality system according to the Directive 98/79/EC, Annex IV excluding (4).

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava on August 26th, 2018

Digitally signed by Talpis Andrei
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