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

EC CERTIFICATE

No. 2018-IVD/QS-004

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 devices 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

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. 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, requirements and measures applied by the manufacturer are presented in the Audit Report No. 320051 and the Final protocol No. 320051/2018.

This Certificate is issued under the following conditions:

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. The certificate remains valid until the manufacturing conditions or the quality system are changed but until August 25th, 2023 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer. For the placing on the market of the above referenced models of in vitro diagnostic medical devices covered by this certificate, an EC design-examination certificate according to the Directive 98/79/EC, Annex IV (4) is required.

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

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

Issued in Bratislava on August 26th, 2018

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