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

EC Design-Examination Certificate

No. 2019-IVD/DE-001

issued in compliance with the Council Directive 98/79/EC on diagnostic medical devices in vitro as amended, which is implemented by the Slovak Government Decree No. 569/2001 Coll. as amended, for the self-testing devices

SureScreen ST FOB – selftesting

(The immunological fecal occult blood testing)

manufactured by company

EUROLAB LAMBDA a.s.
T.Milkina 2, 917 01 Trnava, Slovak republic

The Notified Body No. 2265 has performed design-examination of the devices and certifies that the requirements of Annex III.6 of the Directive 98/79/EC have been met. The devices description and details on the examination are presented in the Final protocol No. 320055/2019.

This certificate is issued under the following conditions:

It applies only to the design of the above referenced models of the diagnostic medical devices in vitro and it does not imply the Notified Body executed any surveillance or control of its manufacture. The manufacturer is obligated to assure that all diagnostic medical devices in vitro 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 January 10th, 2024 at the latest. The certificate validity is conditional upon fulfillment of relevant legal and other requirements by manufacturer.

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, on January 11th, 2019