

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

BATCH RELEASE DECISION

No. HIV210122

issued in compliance with Annex IV.6 of the Council Directive 98/79/EC as amended.

Based on test results and the certificate(s) of analysis submitted to the Notified Body No. 2265 relating to following batch of in vitro diagnostic medical devices:

Product Name: One Step HIV 1+2 Test (Serum/Plasma)

Catalog No.: Cassette C10-20 Brand Name: Coretests® Batch No.: 20210122

Manufacturing Date: January 23, 2021 Expiry Date: January 21, 2023 Quantity: 200549 pcs

manufactured by the company

Core Technology Co., Ltd.

Registered Address: Room 100, C Building No. 29, Life Park Road, Changping District,

Beijing 102206, People's Republic of China

Manufacture Address: No. 30, Area 9, Douda Avenue, Fangshan District, Beijing 102433, People's Republic of China

the Notified Body No. 2265 agrees with placing of the above specified batch of the in vitro diagnostic medical devices (Annex II, List A) on the market.



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



At Bratislava, on August 17th, 2021