MCCAA

MALTA COMPETITION AND CONSUMER AFFAIRS AUTHORITY

TECHNICAL REGULATIONS DIVISION

REGULATORY AFFAIRS DIRECTORATE

5th May 2020

Registration of Manufacturers and Medical Devices of In-Vitro Diagnostic Medical Devices

The competent authority confirms the registration for **Manufacturers Name:** Accobiotech SDN BDH. located at **Manufacturers address:** No 11, Jalan Bukit 27, Banda Seri Alam, Masai, 81750 Johor, Malaysia with **European Authorised Representative name**: Certiva Limited. located at **European Authorised Representative address**: 3rd Floor, 207 Regent Street London, W18 3HH. The registration of the following In-Vitro diagnostic medical devices has been recorded:

Product Name/Type	Device Reference
Acco COVID-19 IgM/IgG	DVC-MT-20-05-000215

The registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnostic medical device", and that you have classified them correctly taking into account the intended purpose(s) and mode(s) of action. Kindly note that you should be operating under the In-Vitro Diagnostic Medical Devices Directive for the listed registered products, by fully complying with the essential requirements, CE marking those products and labelling them as such.

Please inform us of any changes to:

- The company information
- Additional generic groups of devices (not individual products with an existing generic group)
- Discontinuation of a generic group of devices

Kindly note that this letter does not represent any form of accreditation or approval by the Maltese Competent Authority.

Sincerely,

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Edward Xuereb
Director General
Technical Regulations Division
Malta Competition and Consumer Affairs Authority

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