

CERTIFICATE **TUV NORD**

Management system as per **Good Distribution Practice for Medical Devices (GDPMD)** Medical Device Act 2012 (Act 737) of Malaysia

In accordance with TÜV NORD CERT procedures, it is hereby certified that

FC-BIOS

Excellence in Laboratory and Process Supplies

FC-BIOS SDN BHD (188200-H)
31 & 33, Jalan SS 15/4B,
47500 Subang Jaya,
Selangor D.E.,
Malaysia.

applies a management system in line with the above standard for the following scope

Local Authorised Representative, Importation, Storage and Handling, Warehousing, Repackaging, Labeling and Distribution of In Vitro Diagnostic Medical Device for Clinical Chemistry, Immuno Chemistry, Haematology, Histology, Microbiology – Culture and Molecular Biology, Medical consumables, Microtome accessories, Automatic Sensitivity Testing Reader, Centrifuges, Autoclaves, Liquid Nitrogen Storage Dewars and Freezers.

Installation, Testing, Commissioning and Maintenance of Automatic Sensitivity Testing Reader, Centrifuges, Autoclaves, Liquid Nitrogen Storage Dewars and Freezers

Special Storage and handling condition : 2 °C ~ 8 °C
-20 °C and below
10 °C ~ 30 °C

Outsourced activity: transportation / courier

This GDPMD Certification is provisional subject to the condition that the Medical Devices is registered.

Certificate Registration No. 222 15036

Valid until 2018-05-31

Initial Certification 2015-06-01



Ir. Bill Kong
Certification Body
at TUV NORD (M) SDN BHD

TUV NORD (M) SDN BHD
MDA Registration No: MDA/CAB - 008
No. 20, Jalan Tiara 3,
Tiara Square,
Taman Perindustrian UEP,
47600 Subang Jaya,
Malaysia.
2015-06-01

This certification was conducted in accordance with the TUV NORD (M) SDN BHD auditing and certification procedures and is subject to regular surveillance audits.

