

CERTIFICATE

Management system as per **Good Distribution Practice for Medical Devices (GDPMD)**

MDA/RR No.1, November 2015 pursuant to Appendix 4, Third Schedule of Medical Device Regulation 2012

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

FC-BIOS

Excellence in Laboratory and Process Supplies

FC-BIOS SDN BHD
31 & 33, Jalan SS 15/4B,
47500 Subang Jaya,
Selangor, Malaysia

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

Local Authorised Representative, Import, Storage and Handling, Warehousing, Secondary Assembly, Distribution and Documentation of In vitro Diagnostic, Laboratory Equipment and Electro-Mechanical Devices.

Installation, Testing and Commissioning, Maintenance and Calibration of Electro-Mechanical Devices.

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

Outsourced process: Distribution (including Transportation)

Certificate Registration No. 222 15036

Valid from 2018-06-01

Valid until 2021-05-31

Initial Certification 2015



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

TÜV NORD (M) SDN BHD
MDA Registration No: MDA/CAB - 008
No. 20, Jalan Tiara 3,
Tiara Square,
Taman Perindustrian UEP,
47600 Subang Jaya,
Malaysia.
2018-06-01

A N N E X

to Certificate Registration No. 222 15036

Good Distribution Practice for Medical Devices (GDPMD)

MDA/RR No.1, November 2015 pursuant to Appendix 4, Third Schedule of Medical Device Regulation 2012

FC-BIOS SDN BHD (188200-H)

31 & 33, Jalan SS 15/4B,
47500 Subang Jaya,
Selangor, Malaysia

Certificate Registration No.	Location	Function
222 15036-001	FC-Bios Sdn Bhd (HQ) 31 & 33, Jalan SS 15/4B, 47500 Subang Jaya, Selangor, Malaysia	Local Authorised Representative, Import and Documentation of In vitro Diagnostic, Laboratory Equipment and Electro-Mechanical Devices. Installation, Testing and Commissioning, Maintenance and Calibration of Electro-Mechanical Devices.
222 15036-002	FC-Bios Sdn Bhd (Warehouse 1) 28, Lot 778, Jalan Subang 4, Persiaran Subang Permai, Sg Penaga Industrial Park 47500 Subang Jaya, Selangor, Malaysia.	Storage and Handling, Warehousing, Secondary Assembly and Distribution of In vitro Diagnostic, Laboratory Equipment and Electro-Mechanical Devices. Special storage and handling condition: 2-8 °C -20 °C and below 10-30 °C
222 15036-003	FC-Bios Sdn Bhd (Warehouse 2) 43, Lot 778, Jalan Subang 4, Persiaran Subang Permai, Sg Penaga Industrial Park 47500 Subang Jaya, Selangor, Malaysia.	Storage and Handling, Warehousing and Distribution of In vitro Diagnostic, Laboratory Equipment and Electro-Mechanical Devices. Special storage and handling condition: N/A
222 15036-004	FC-Bios Sdn Bhd (Warehouse 3) 1, Jalan Subang 4, Persiaran Subang Permai, Sg Penaga Industrial Park 47500 Subang Jaya, Selangor, Malaysia.	Storage and Handling, Warehousing and Distribution of In vitro Diagnostic, Laboratory Equipment and Electro-Mechanical Devices. Special storage and handling condition: N/A

No	DEVICE CATEGORY*
1.	06 In vitro diagnostic devices
2.	16 Laboratory equipment
3.	04 Electro mechanical medical devices

End of the list

Valid from 2018-06-01
Valid until 2021-05-31
Initial Certification 2015



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

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No. 20, Jalan Tiara 3,
Tiara Square,
Taman Perindustrian JEP,
47600 Subang Jaya,
Malaysia.
2018-06-01

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