

# Certificate of Conformity

## Good Distribution Practice for Medical Devices (GDPMD)

This is to certify that:

BMS Diagnostics (M) Sdn Bhd  
Level 7, Menara Biomed,  
No 13, Jalan Cempaka SD 12/5,  
52200 Bandar Sri Damansara,  
Kuala Lumpur  
Malaysia

Holds Certificate No:

**FS 612193**

has complied with the Regulatory Requirements of GDPMD as stipulated in MDA/RR No. 1: November 2015 First Revision pursuant to Appendix 4, Third Schedule of Medical Device Regulations 2012

### Scope of certification

Local Authorised Representative, import, storage and handling, warehousing, distribution (transportation), installation, testing & commissioning, maintenance, calibration and documentation (traceability) for medical device as listed in Annex 1.

[With outsourced transportation activities to third party service provider]

[There is special requirement on storage and handling of medical device being distributed which is 2°C to 8°C, -25°C to -15°C and -65°C to -80°C]



For and on behalf of BSI

Evelyn Chye, Managing Director

Originally registered: 2015-04-29

Latest Revision Date: 2023-04-17

Effective Date: 2023-04-29

Expiry Date: 2026-04-28



Page 1 of 2

CAB Registration No : MDA/CAB-005

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Certificate No: **FS 612193**

Location	Registered Activities
BMS Diagnostics (M) Sdn Bhd Level 7, Menara Biomed, No 13, Jalan Cempaka SD 12/5, 52200 Bandar Sri Damansara, Kuala Lumpur Malaysia	Local Authorised Representative, import, storage and handling, warehousing, distribution (transportation), installation, testing & commissioning, maintenance, calibration and documentation (traceability) for medical device as listed in Annex 1. [With outsourced transportation activities to third party service provider] [There is special requirement on storage and handling of medical device being distributed which is 2°C to 8°C, -25°C to -15°C and -65°C to -80°C]
BMS Diagnostics (M) Sdn Bhd Lot 830-A, 830-B & 830-M, Jalan Kusta, Kawasan Industri Kampung Jaya, 47000 Sungai Buloh, Selangor Darul Ehsan Malaysia	Local Authorised Representative, import, storage and handling, warehousing, distribution (transportation), installation, testing & commissioning, maintenance, calibration and documentation (traceability) for medical device as listed in Annex 1. [With outsourced transportation activities to third party service provider] [There is special requirement on storage and handling of medical device being distributed which is 2°C to 8°C, -25°C to -15°C and -65°C to -80°C]

Originally registered: 2015-04-29  
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Page 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

Printed copies can be validated at telephone +603 9212 9638

Further clarifications regarding the scope of this certificate and the applicability of GDPMD requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, UK. Tel: +44 845 080 9000

Malaysia Headquarter: Suite 29.01, Level 29, The Gardens North Tower, Mid Valley City, Lingkaran Syed Putra, 59200 Kuala Lumpur.

A Member of the BSI Group of Companies.

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**ANNEX 1 : List of devices dealt with by the establishment -**

<b>No.</b>	<b>DEVICE CATEGORY</b>
1	04 Electro mechanical medical devices
2	05 Hospital hardware
3	06 In vitro diagnostic devices
4	09 Reusable devices
5	10 Single-use devices
6	16 Laboratory equipment
7	17 Medical software
8	18 Others: Assisted Reproductive Labware; Cryopreservation Solution



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