

Certificate of Conformity

Good Distribution Practice for Medical Devices (GDPMD)

This is to certify that:

Ambang Gemilang Saintifik Sdn Bhd
No. 10, Jalan Batu Belah 27/96
Section 27
40400 Shah Alam
Selangor
Malaysia

Holds Certificate No:

FS 611565

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, Distribution (including transportation), Warehousing, Storage & Handling, and Documentation (including traceability) of Medical Devices listed in Annex 1.
[Outsourced delivery service to third party service providers, Outsourced Testing & Commissioning to Medinnova Services Sdn. Bhd.]



For and on behalf of BSI

Evelyn Chye, Managing Director

Originally registered: 2014-04-09
Latest Revision Date: 2023-04-03

Effective Date: 2023-04-09
Expiry Date: 2026-04-08



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CAB Registration No : MDA/CAB-005

...making excellence a habit.™

Certificate No: **FS 611565**

| Location | Registered Activities |
|--|---|
| Ambang Gemilang Saintifik Sdn Bhd No. 10, Jalan Batu Belah 27/96 Section 27 40400 Shah Alam Selangor Malaysia | Local Authorised Representative, Import, Distribution (including transportation), Warehousing, Storage & Handling, and Documentation (including traceability) of Medical Devices listed in Annex 1. [Outsourced delivery service to third party service providers, Outsourced Testing & Commissioning to Medinnova Services Sdn. Bhd.] |

| | |
|--|---|
| Ambang Gemilang Saintifik Sdn Bhd No. 8 & 12, Jalan Batu Belah 27/96 Section 27 40400 Shah Alam Selangor Malaysia | Local Authorised Representative, Import, Distribution (including transportation), Warehousing, Storage & Handling, and Documentation (including traceability) of Medical Devices listed in Annex 1. [Outsourced delivery service to third party service providers, Outsourced Testing & Commissioning to Medinnova Services Sdn. Bhd.] |
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ANNEX 1 : List of devices dealt with by the establishment -

| No. | DEVICE CATEGORY |
|-----|--------------------------------|
| 1 | 06 In vitro diagnostic devices |
| 2 | 10 Single-use devices |
| 3 | 16 Laboratory equipment |



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

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A Member of the BSI Group of Companies.