

# Certificate of Conformity

## Good Distribution Practice for Medical Devices (GDPMD)

This is to certify that:

Setia Medik Sdn Bhd  
Wisma Setia, No.12, Jalan Hi-Tech 3/1  
Semenyih Hi-Tech 3 Industrial Park  
Off Jalan Sungai Lalang  
43500 Semenyih  
Selangor, Malaysia  
[Ms. Loo Lay Hui, Tel: 03-8727 5626]

Holds Certificate No:

**FS 612056**

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 Authorized Representative (LAR), Import, Storage & Handling, Warehousing, Distribution  
(including transportation) and documentation (including traceability) of Medical Devices as listed  
in Annex 1.

[With outsourced transportation activities to GD Express Sdn. Bhd.]

[With special storage & handling condition of  $\leq 25^{\circ}\text{C}$  to  $\leq 30^{\circ}\text{C}$  for certain medical device being  
distributed by the establishment]

## Not Valid for Commercial Use

For and on behalf of BSI

Evelyn Chye, General Manager

Originally registered: 2015-05-13  
Latest Revision Date: 2018-04-13

Effective Date: 2018-05-13  
Expiry Date: 2021-05-12



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CAB Registration No : MDA/CAB-005

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 22424211

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: Unit 10-03, Level 10, Tower A, The Vertical Business Suites, Bangsar South, No. 8, Jalan Kerinchi, 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 -**

No.	DEVICE CATEGORY
1	18 – Non-active medical devices with measuring function (gke)
2	18 – Non-active medical devices for disinfecting, cleaning, rinsing (Dr. Weigert)
3	18 – Non-active medical devices for sterilization paper bags (PMG)



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