

CERTIFICATE OF CONFORMITY

Good Distribution Practice For Medical Device



This is to certify:

**ADVANCE ALTIMAS SDN. BHD.
NO. 15-1, 1ST FLOOR
JALAN PJS 8/10, SUNWAY MENTARI
46150 PETALING JAYA
SELANGOR DARUL EHSAN
MALAYSIA**

TEL. NO. : 016-2236394

Certificate no. : **GDPMD 00393**

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

Scope of certification: **DISTRIBUTION (INCLUDING TRANSPORTATION),
INSTALLATION, TESTING AND COMMISSIONING
(INCLUDING THE REQUIRED FACILITIES), MAINTENANCE
AND CALIBRATION (INCLUDING THE REQUIRED
FACILITIES) AND DOCUMENTATION OF MEDICAL DEVICES.**

Special storage and handling conditions: ***Not Applicable***

Issue Date : **16 October 2020**

Expiry Date : **21 June 2021**

Attachment:

1. List of devices;
2. List of outsourced activities.



MOHD AZANUDDIN SALLEH
Chief Executive Officer
SIRIM QAS International Sdn. Bhd.

This certificate is granted subject to the terms and conditions as stated in the Certification Agreement.

SIRIM QAS International Sdn. Bhd. (Co. No. 410334 - X)

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<http://www.sirim-qas.com.my>

<http://www.malaysiancertified.com.my>

LIST OF DEVICES DEALT WITH BY THE ESTABLISHMENT

No.	DEVICE CATEGORY*
1.	(02) ANESTHETIC AND RESPIRATORY DEVICES
2.	(09) REUSABLE DEVICES
3.	(10) SINGLE-USE DEVICES
4.	(12) DIAGNOSTIC AND THERAPEUTIC RADIATION DEVICES
5.	(17) MEDICAL SOFTWARE
6.	(18) OTHERS: IMAGING DEVICES UTILISING NON-IONIZING RADIATION
7.	(18) OTHERS: MONITORING DEVICES OF NON-VITAL PHYSIOLOGICAL PARAMETERS
8.	(18) OTHERS: MONITORING DEVICES OF VITAL PHYSIOLOGICAL PARAMETERS

*List of device categories:

- 01 Active implantable devices
- 02 Anesthetic and respiratory devices
- 03 Dental Devices
- 04 Electro mechanical medical devices
- 05 Hospital hardware
- 06 In vitro diagnostic devices
- 07 Non-active implantable devices
- 08 Ophthalmic and optical devices
- 09 Reusable devices
- 10 Single-use devices
- 11 Assistive products for persons with disability
- 12 Diagnostic and therapeutic radiation devices
- 13 Complementary therapy devices
- 14 Biologically-derived devices
- 15 Healthcare facility products and adaptations
- 16 Laboratory equipment
- 17 Medical software
- 18 Others: Please specify with justification for any additional categories

