

CERTIFICATE OF CONFORMITY

Good Distribution Practice For Medical Device

This is to certify:

RITZ MEDICAL SDN. BHD.
918, BLOCK B2, PUSAT DAGANG SETIA JAYA 9
JALAN PJS 8/9
46150 PETALING JAYA
SELANGOR DARUL EHSAN
MALAYSIA

TEL. NO. : 03-78770377

Certificate no. : **GDPMD 00202**

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: **IMPORT, STORAGE AND HANDLING, DISTRIBUTION (INCLUDING TRANSPORTATION), INSTALLATION, TESTING AND COMMISSIONING (INCLUDING THE REQUIRED FACILITIES), MAINTENANCE AND CALIBRATION (INCLUDING THE REQUIRED FACILITIES) OF MEDICAL DEVICES AS AN AUTHORIZED REPRESENTATIVE.**

Special storage and handling conditions:

•Controlled room temperature less than 30°C for the disposable angiographic products.

Issue Date : **06 September 2018**

Expiry Date : **06 August 2021**

Attachment:

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



MOHD AZANUDDIN SALLEH
Managing Director
SIRIM QAS International Sdn Bhd

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

ANNEX

LIST OF DEVICES DEALT WITH BY THE ESTABLISHMENT

NO.	DEVICE CATEGORY*
1.	(02) ANAESTHETIC AND RESPIRATORY DEVICES
2.	(04) ELECTRO MECHANICAL MEDICAL DEVICES
3.	(05) HOSPITAL HARDWARE
4.	(07) NON-ACTIVE IMPLANTABLE DEVICES
5.	(10) SINGLE-USE DEVICES
6.	(11) ASSISTIVE PRODUCTS FOR PERSONS WITH DISABILITY

***LIST OF DEVICE CATEGORIES:**

- 01 Active implantable devices
- 02 Anaesthetic 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 Healthcare facility products and adaptations
- 15 Healthcare facility products and adaptations
- 16 Laboratory equipment
- 17 Medical software
- 18 Others: Please specify with justification for any additional categories