



MDA/CAB-013



CERTIFICATE OF CONFORMITY

Good Distribution Practice For Medical Device

This is to certify : **ISOLAB SDN. BHD. (428427-T)**

No. 5, Jalan Anggerik Mokara 31/46,
Kota Kemuning,
40460 Shah Alam, Selangor Darul Ehsan,
Malaysia.

Certificate Number : **610131**

has complied with the Regulatory Requirements of GDPMD as stipulated in MDA/RR NO. 1 July 2013 pursuant to Appendix 4, Third Schedule of Medical Device Regulations 2012

Scope of Certification : **Import, Storage, Warehousing, Distribution, Transportation and Documentation as Local Authorized Representative**

(Outsourced process: Transportation)
Secondary Assembly Including Repacking

Exclusion:

- CI 31-36 Secondary Assembly Including Repacking
- CI 28 Specific Requirements for Active Medical Devices
- CI 27 Specific Traceability Requirements for Implantable Medical Devices

List of devices dealt with by the establishment- Refer to Annexure 1

Date of Initial Certification : **10 February 2017**

Date of Issue/Reissue : **10 February 2017**

Renewal Due : **22 November 2019**



E. Nacheyakala
Managing Director

This certificate is subject to the company maintaining its system to the required standards, which will be monitored by KGS.
The use of this Certificate and the KGS Certification Mark are subject to the Regulations Applicable to Holders of KGS Certification Sdn. Bhd.

KGS Certification Sdn. Bhd. (824092-A)

No. 15, Lorong BLM 5/4, Bandar Laguna Merbok, 08000 Sungai Petani, Kedah Darul Aman, Malaysia.
Tel: 604 441 1524 Fax: 604 441 0610 Email: kgscertification@gmail.com www.kgscert.com

The Certificate remains the property of KGS and shall be returned when requested. It may only be reproduced in its entirety and without change.



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Device Category

10. Single-Use Devices

14. Biologically-Derived Devices



KGS

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Annexure 1 – Page 1 of 1

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No.	Name of Medical Device	Manufacturer	Brand/Model
1.	HCG One-Step Pregnancy Test Strips	Shanghai Chemtron Biotech Co., Ltd, China.	ISO-CHEK
2.	HCG Pregnancy Test Cassettes (25MIU/ML)	Shanghai Chemtron Biotech Co., Ltd, China.	ISO-CHEK
3.	Absorbent Gauze Roll	ShaoxingFuqing Medical Products Co., Ltd.	ISO-CARE
4.	Absorbent Gauze Swab	ShaoxingFuqing Medical Products Co., Ltd.	ISO-CARE
5.	X-RAY Detectable Gauze Roll	ShaoxingFuqing Medical Products Co., Ltd.	ISO-CARE
6.	X-RAY Detectable Gauze Swab	ShaoxingFuqing Medical Products Co., Ltd.	ISO-CARE
7.	Erythrocyte Sedimentation Rate (ESR) Analyzer	labONE Inc., India.	labONE
8.	Vacuum Blood Collection Tubes	Zhejiang Gongdong Medical Technology Co.,Ltd, China.	Golden Vac-Tube
9.	Tibilia TB Antigen Rapid Test Device	Hangzhou Genesis Biodetection & Biocontrol, China Technology Co., Ltd.	Tibilia

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