

DEVICE DETAILS

NAME OF DEVICE	GLUNEO LITE BLOOD GLUCOSE MONITORING SYSTEM
ESTABLISHMENT NAME	REVO HEALTHCARE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	IVDC2390019-28353
BRAND NAME	GLUNEO LITE/ INFOPIA
MEDICAL DEVICE CATEGORY	Device for self-diagnosis: device for the measurement of blood Sugar
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	The IGM-1003A Blood Glucose Monitoring System is used for the quantitative measurement of glucose level in whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings. IGM-1003A Blood Glucose Monitoring System is for self-testing outside the body (in-vitro diagnostic use only).
DEVICE INTENDED PURPOSE	The IGM-1003A Blood Glucose Monitoring System is intended for use outside the body only (in-vitro diagnostic use) and self-testing. The test results make it easier for your doctor to access your metabolic control. However, the self-testing should not take the place of overall diabetes management assessment from your doctor. It should be used only for testing blood glucose (sugar), and only with fresh capillary and venous whole blood samples. The IGM -1003A Blood Glucose Monitoring System is intended for use in the home and in professional setting to monitor blood glucose levels.
VALIDITY DATE OF REGISTRATION	02/05/2019 - 01/05/2024

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	GluNEO® Lite Blood Glucose Meter	INFM001L
2	GluNEO® Lite Blood Glucose Test Strips	INFS001L
3	GluNEO® Lite Glucose Control Solution (Low)	INFCL001L
4	GluNEO® Lite Glucose Control Solution (Normal)	INFCN001L
5	GluNEO® Lite Glucose Control Solution (High)	INFCH001L
6	Lancing Device	N/A
7	Lancets	N/A