



DEVICE DETAILS

NAME OF DEVICE	GM85
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC45645259517
BRAND NAME	SAMSUNG ELECTRONIC CO., LTD
MEDICAL DEVICE CATEGORY	MD 1201 - Imaging devices utilising ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THE GM85 SYSTEM IS INTENDED TO BE USED FOR CAPTURING DIGITAL X-RAY IMAGES OF VARIOUS PARTS OF THE BODY INCLUDING THE HEAD, CHEST, SPINE, ABDOMEN, JOINTS, HANDS, FEET AND OTHER ORGANS. ITS INTENDED USE DOES NOT INCLUDE MAMMOGRAPHY. THE GM85 DIGITAL MOBILE X-RAY IMAGING SYSTEM IS USED TO TAKE AND STORE IMAGE FOR DIAGNOSIS OF PATIENTS. IT MAINLY CONSISTS OF THE X-RAY GENERATOR, DETECTOR, X-RAY TUBE, CONTROL PANEL, COLLIMATOR, MOBILE SYSTEM FOR MOVEMENT AND THE S-STATION (OPERATION SOFTWARE).
DEVICE INTENDED PURPOSE	THE GM85 IS INTENDED TO BE USED FOR CAPTURING DIGITAL X-RAY IMAGES OF VARIOUS PARTS OF THE BODY INCLUDING THE HEAD, CHEST, SPINE, ABDOMEN, JOINTS, HANDS, FEET, AND OTHER ORGANS BY A QUALIFIED/TRAINED DOCTOR OR TECHNICIAN. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHIC APPLICATIONS.
VALIDITY DATE OF REGISTRATION	21/06/2022 - 20/06/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Digital Diagnostic Mobile X-ray System	GM85
2	Digital Flat Panel X-ray Detector	S4335-W
3	Digital Flat Panel X-ray Detector	S4343-W
4	Digital Flat Panel X-ray Detector	S3025-W
5	Digital Flat Panel X-ray Detector	S4335-AW
6	Digital Flat Panel X-ray Detector	S4343-AW
7	Digital Flat Panel X-ray Detector	FXRD-2530VAW PLUS (Brand name: S3025-AW)
8	Digital Flat Panel X-ray Detector	FXRD-2530VAW (Brand name: S3025-AWM)

NO	NAME OF DEVICE	IDENTIFIER
9	Digital Flat Panel X-ray Detector	S4335-AWM
10	Digital Flat Panel X-ray Detector	S4343-AWM
11	DAP	DGR-ACCSDH
12	High Voltage Generator	SMG-40
13	High Voltage Generator	Venus-40-M
14	X-ray Tube	LUC-13L
15	X-ray Tube	LUC-11L
16	X-ray Tube	XRR-3332X

