



DEVICE DETAILS

NAME OF DEVICE	DIAGNOSTIC X-RAY SYSTEM GC85A
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC66959327217
BRAND NAME	SAMSUNG ELECTRONIC CO., LTD
MEDICAL DEVICE CATEGORY	MD 1201 - Imaging devices utilising ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THE GC85A DIGITAL X-RAY IMAGING SYSTEM IS TO BE USED TO TAKE AND STORE IMAGE FOR DIAGNOSIS OF PATIENTS. IT CONSISTS OF THE HIGH VOLTAGE GENERATOR (HVG), CEILING SUSPENSION, DETECTOR, X-RAY TUBE, PATIENT TABLE, WALL STAND, COLLIMATOR AND ETC.
DEVICE INTENDED PURPOSE	THE GC85A DIGITAL X-RAY IMAGING SYSTEM IS INTENDED FOR USE IN GENERATING RADIOGRAPHIC IMAGES OF HUMAN ANATOMY BY A QUALIFIED/TRAINED DOCTOR OR TECHNICIAN. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHIC APPLICATIONS.
VALIDITY DATE OF REGISTRATION	25/08/2022 - 24/08/2027

LIST OF DEVICE



NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic X-ray System	GC85A
2	X-ray tube	E7869X
3	X-ray tube	E7252X
4	Diagnostic X-ray High Voltage Generator	GXR-82
5	Diagnostic X-ray High Voltage Generator	GXR-52
6	Diagnostic X-ray High Voltage Generator	ZR75PN80
7	Diagnostic X-ray High Voltage Generator	ZR75PN50
8	Collimator	SDR-OGCL80U
9	Collimator	SDR-OGCL83U
10	Collimator	SDR-OGCL81U
11	Collimator	SDR-OGCL83N

NO	NAME OF DEVICE	IDENTIFIER
12	System Cabinet	SDR-OGCA80U
13	System Cabinet	SDR-OGCA75A
14	System Cabinet	SDR-OGCA75B
15	System Cabinet	SDR-OGCA75C
16	System Cabinet	SDR-OGCA81A
17	System Cabinet	SDR-OGCA81B
18	Remote Controller	SDR-OGRC80U
19	Remote Controller	SDR-OGRC81J
20	Remote Controller	SDR-OGRC71A
21	CIB	SDR-OGCI80U
22	Digital Flat Panel X-ray Detector	S4335-W
23	Digital Flat Panel X-ray Detector	S4343-W
24	Digital Flat Panel X-ray Detector	S3025-W
25	Digital Flat Panel X-ray Detector	S4335-AW
26	Digital Flat Panel X-ray Detector	S4343-AW
27	Digital Flat Panel X-ray Detector	FXRD-2530VAW PLUS (Brand name: S3025-AW)
28	Digital Flat Panel X-ray Detector	FXRD-2530VAW (Brand name: S3025-AWM)
29	Digital Flat Panel X-ray Detector	S4335-AWM
30	Digital Flat Panel X-ray Detector	S4343-AWM
31	Digital Flat Panel X-ray Detector	F4335-AW
32	Digital Flat Panel X-ray Detector	F4343-AW
33	Wall Stand	SDR-OGST80U
34	Wall Stand	SDR-OGST73A
35	Wall Stand	SDR-OGST73B
36	Wall Stand	SDR-OGST73C
37	Ceiling Suspension	SDR-OGTS80U

NO	NAME OF DEVICE	IDENTIFIER
38	Ceiling Suspension	SDR-OGTS80N
39	Patient Table	SDR-OGTA80U
40	Foot Switch(Stand)	SDR-OGSF10A
41	Foot Switch(Stand)	SDR-OGSF80L
42	Foot Switch(Table)	SDR-OGSF70A
43	Foot Switch(Table)	SDR-OGSF81L
44	Auto Stitching Stand	SDR-OGAS70A
45	Grid Holder	SDR-OGGH70A
46	Compressing Belt	SDR-OGCB70A
47	Detector Holder	SDR-OGDH70A
48	Lateral Support Bar	SDR-OGBA80N
49	Lateral Support Bar	SDR-OGBA81N
50	Wired X-ray Exposure switch	F29-9A