



DEVICE DETAILS

NAME OF DEVICE	DIAGNOSTIC X-RAY SYSTEM GF85 (GF85-3P, GF85-SP)
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC9202825-205276
BRAND NAME	SAMSUNG ELECTRONIC CO., LTD
MEDICAL DEVICE CATEGORY	MD 1200 - DEVICES FOR IMAGING
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The GF85(GF85-3P, GF85-SP) digital X-ray imaging system are to be used to take and store image for diagnosis of patients. It consists of the High voltage generator (HVG), Detector, X-ray tube, Floor mounted stand, Patient table, Wall stand, Collimator and other components etc.
DEVICE INTENDED PURPOSE	The GF85(GF85-3P, GF85-SP) 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	13/06/2025 - 12/06/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic X-ray System	GF85-3P
2	Diagnostic X-ray System	GF85-SP
3	X-ray tube	H2100X
4	X-ray tube	H1080X
5	X-ray tube	H1086X
6	X-ray tube	E7254FX
7	X-ray tube	E7252X
8	X-ray tube	E7843X
9	Diagnostic X-ray High Voltage Generator	Cetus 80R01
10	Diagnostic X-ray High Voltage Generator	Cetus 65R01

NO	NAME OF DEVICE	IDENTIFIER
11	Diagnostic X-ray High Voltage Generator	Cetus 50R01
12	Diagnostic X-ray High Voltage Generator	Cetus 40R03
13	Collimator	SDR-OGCL20P
14	Collimator	SDR-OGCL21P
15	System Cabinet	SDR-OGCA20P
16	System Cabinet	SDR-OGCA21P
17	CIB	SDR-OGCI20P
18	Digital Flat Panel X-ray Detector	S4335-AW
19	Digital Flat Panel X-ray Detector	S4343-AW
20	Digital Flat Panel X-ray Detector	FXRD-2530VAW PLUS (Brand name: S3025-AW)
21	Digital Flat Panel X-ray Detector	FXRD-2530VAW (Brand name: S3025-AWM)
22	Digital Flat Panel X-ray Detector	S4335-AWM
23	Digital Flat Panel X-ray Detector	S4343-AWM
24	Digital Flat Panel X-ray Detector	F4335-AW
25	Digital Flat Panel X-ray Detector	F4343-AW
26	Wall Stand	SDR-OGST21P
27	Wall Stand	SDR-OGST20P
28	Tube Stand	SDR-OGTU20P
29	Patient Table	SDR-OGTA20P
30	Patient Table	SDR-OGTA21P
31	Auto Stitching Stand	SDR-OGAS70A
32	Weight distribution cap	SDR-OGWD80U
33	Grid Holder	SDR-OGGH70A
34	Compressing Belt	SDR-OGCB20P
35	Detector Holder	SDR-OGDH70A
36	Lateral Support Bar	SDR-OGBA20P

NO	NAME OF DEVICE	IDENTIFIER
37	Wired X-ray Exposure switch	F29-9A
38	DAP	DGR-ACCSHD



MEDICAL DEVICE AUTHORITY