



## DEVICE DETAILS

NAME OF DEVICE	GM85 (C-TYPE, F-TYPE, FIT-TYPE)
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC5394423-134640
BRAND NAME	SAMSUNG ELECTRONIC CO.LTD.
MEDICAL DEVICE CATEGORY	MD 1201 - Imaging devices utilising ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The GM85 digital X-ray imaging system consists of the built-in high voltage generator, X-ray tube, control panel, mobile system for movement, detector and the S-station (operation software).
DEVICE INTENDED PURPOSE	The GM85 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	08/06/2023 - 07/06/2028

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Digital Diagnostic Mobile X-ray System	GM85 (C-Type)
2	Digital Diagnostic Mobile X-ray System	GM85 (F-Type)
3	Digital Diagnostic Mobile X-ray System	GM85 (Fit-Type)
4	Digital Flat Panel X-ray Detector	S4335-W
5	Digital Flat Panel X-ray Detector	S4343-W
6	Digital Flat Panel X-ray Detector	S3025-W
7	Digital Flat Panel X-ray Detector	S4335-AW
8	Digital Flat Panel X-ray Detector	S4343-AW
9	Digital Flat Panel X-ray Detector	FXRD-2530VAW PLUS (Brand name: S3025-AW)
10	Digital Flat Panel X-ray Detector	FXRD-2530VAW (Brand name: S3025-AWM)
11	Digital Flat Panel X-ray Detector	S4335-AWM
12	Digital Flat Panel X-ray Detector	S4343-AWM
13	Digital Flat Panel X-ray Detector	F4335-AW

NO	NAME OF DEVICE	IDENTIFIER
14	Digital Flat Panel X-ray Detector	F4343-AW
15	DAP	DGR-ACCSHD
16	High Voltage Generator	SMG-40
17	High Voltage Generator	Venus-40-M
18	X-ray Tube	LUC-13L
19	X-ray Tube	LUC-11L
20	X-ray Tube	XRR-3332X
21	Collimator	SDR-OGCL40U
22	Collimator	SDR-OGCL41U
23	Collimator	SDR-OGCL30L
24	Battery	EGI-D3S1P
25	Battery	SDB-3S1PA
26	Battery	ELT-3S1PA