



DEVICE DETAILS

NAME OF DEVICE	GR40CW
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB76751327417
BRAND NAME	SAMSUNG ELECTRONIC CO., LTD
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THE GR40CW DIGITAL X-RAY IMAGING SYSTEM CONSISTS OF DETECTOR, POWER SUPPLY BOX, BATTERY PACK, BATTERY CHARGER, ACCESS POINT, CIB(CONTROL INTERFACE BOX), WORKSTATION, BARCODE SCANNER AND MAIN CABLE. THIS SYSTEM IS USED TO CAPTURE IMAGES BY TRANSMITTING X-RAY TO A PATIENT'S BODY. THE X-RAY PASSING THROUGH A PATIENT'S BODY IS SENT TO THE DETECTOR AND THEN CONVERTED INTO ELECTRICAL SIGNALS. THESE SIGNALS GO THROUGH THE PROCESS OF AMPLIFICATION AND DIGITAL DATA CONVERSION IN THE SIGNAL PROCESS DEVICE BEFORE BEING SENT TO THE S-STATION (OPERATION SOFTWARE) AND SAVED IN DICOM FILE, A STANDARD FOR MEDICAL IMAGING. THE CAPTURED IMAGES ARE SENT TO THE PICTURE ARCHIVING & COMMUNICATION SYSTEM (PACS) SERVER, AND CAN BE USED FOR READING IMAGES.
DEVICE INTENDED PURPOSE	IT IS INTENDED FOR USE IN GENERAL PROJECTION RADIOGRAPHIC APPLICATIONS WHEREVER CONVENTIONAL SCREEN-FILM SYSTEMS OR CR SYSTEMS MAY BE USED.
VALIDITY DATE OF REGISTRATION	25/08/2022 - 24/08/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Retrofit kit	GR40CW
2	Digital Flat Panel X-ray Detector	S4335-W
3	Digital Flat Panel X-ray Detector	S4335-WV
4	Digital Flat Panel X-ray Detector	S4343-W
5	Digital Flat Panel X-ray Detector	S4335-AW
6	Digital Flat Panel X-ray Detector	S4335-AWV

NO	NAME OF DEVICE	IDENTIFIER
7	Digital Flat Panel X-ray Detector	S4343-AW
8	Digital Flat Panel X-ray Detector	S3025-W
9	Digital Flat Panel X-ray Detector	S4335-AWM
10	Digital Flat Panel X-ray Detector	S4343-AWM
11	Digital Flat Panel X-ray Detector	F4335-AW
12	Digital Flat Panel X-ray Detector	F4343-AW
13	CIB	SDR-OGCI51A
14	CIB	SDR-OGCI51F



MEDICAL DEVICE AUTHORITY