DEVICE DETAILS

NAME OF DEVICE	HM70 EVO DIAGNOSTIC ULTRASOUND APPARATUS
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2875122-101601
BRAND NAME	SAMSUNG MEDISON
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	HM70 EVO is a general purpose, portable, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B-mode, M-mode, Color Doppler mode, Power Doppler mode, PW Spectral Doppler mode, CW Spectral Doppler mode, TDI mode, TDW mode, ElastoScan mode, 3D/4D imaging mode or as a combination of these modes. The HM70 EVO also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The HM70 EVO has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed. The various models of transducers are available and the one probe port of system can be connected. The three probe ports of cart optionally may be connected at the same time. In addition to the initial operational settings for each transducer preprogrammed in the system, user-customized parameter settings for each transducer may be inserted by the operator and stored for recall as needed via the system control panel.
DEVICE INTENDED PURPOSE	The diagnostic ultrasound system and probes are designed to obtain ultrasound images and analyze body fluids. The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular. Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Peripheral vessel and Lung.
VALIDITY DATE OF REGISTRATION	18/08/2022 - 17/08/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic Ultrasound Equipment	HM70 EVO
2	Ultrasound transducer	LA3-16AD
3	Ultrasound transducer	LN5-12
4	Ultrasound transducer	CA2-8AD
5	Ultrasound transducer	C2-8

NO	NAME OF DEVICE	IDENTIFIER
6	Ultrasound transducer	CA1-7AD
7	Ultrasound transducer	CA4-10M
8	Ultrasound transducer	PN2-4
9	Ultrasound transducer	SP3-8
10	Ultrasound transducer	EVN4-9
11	Ultrasound transducer	VN4-8
12	Ultrasound transducer	DP2B
13	Ultrasound transducer	EV2-10A
14	Ultrasound transducer	MMPT3-7
15	Ultrasound transducer	LA2-9S
16	Ultrasound transducer	LS6-15
17	Ultrasound transducer	PA1-5A
18	Ultrasound transducer	PA3-9B
19	Ultrasound transducer	L3-22
20	Ultrasound transducer	LA3-22AI
21	Peripheral device	HM70 EVO CART
22	Peripheral device	ECG cable
23	Peripheral device	Battery Pack
24	Foot switch	FSU-3000S
25	Foot switch	FSU-3000SM
26	Printer	UP-D897
27	Printer	UP-X898MD
28	Printer	UP-D898MD
29	Printer	UP-D25MD
30	Printer	UP-X898MD
31	Printer	UP-D898MD

NO	NAME OF DEVICE	IDENTIFIER
32	Printer	CLP-620NDX
33	Printer	ML-2950