



DEVICE DETAILS

NAME OF DEVICE	HS30 , HS40, HS50, HS60 DIAGNOSTIC ULTRASOUND APPARATUS
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB8706822-104178
BRAND NAME	SAMSUNG MEDISON CO., LTD
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The HS30 and HS40 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D Mode, Color Doppler Mode, Power Doppler Mode, M Mode, PW Spectral Doppler Mode, CW Spectral Doppler Mode, TDI (Tissue Doppler Imaging) Mode, TDW (Tissue Doppler Wave) Mode, ElastoScan Mode, Freehand 3D mode, 3D/4D mode, Dual Mode, Quad Mode or as a combination of these modes. The HS30 and HS40 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 HS30 and HS40 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed. The HS50 and HS60 are a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color M mode, Anatomical mode, Color Doppler mode, Pulsed Wave (PW) Spectral Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, Power Doppler (PD) mode, ElastoScan Mode, 3D/4D/XI STIC imaging mode, Dual mode, Quad mode, Combined mode, Simultaneous mode and Zoom mode. The HS50 and HS60 also give 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 HS50 and HS60 have real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.</p>
DEVICE INTENDED PURPOSE	The ultrasound diagnostic 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,
VALIDITY DATE OF REGISTRATION	19/09/2022 - 18/09/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic Ultrasound Equipment	HS60
2	Diagnostic Ultrasound Equipment	HS50
3	Diagnostic Ultrasound Equipment	HS40
4	Diagnostic Ultrasound Equipment	HS30
5	Diagnostic Ultrasound Equipment	CA1-7AD
6	Ultrasound transducer	CA2-9AD
7	Ultrasound transducer	CA2-6BM
8	Ultrasound transducer	CF4-9
9	Ultrasound transducer	ER4-9
10	Ultrasound transducer	EA2-11B
11	Ultrasound transducer	LA3-14AD
12	Ultrasound transducer	LA2-9A
13	Ultrasound transducer	LA3-16AI
14	Ultrasound transducer	LA4-18BD
15	Ultrasound transducer	LA3-16A
16	Ultrasound transducer	CV1-8AD
17	Ultrasound transducer	V5-9
18	Ultrasound transducer	PA1-5A
19	Ultrasound transducer	PA3-8B
20	Ultrasound transducer	PE2-4
21	Ultrasound transducer	DP2B
22	Ultrasound transducer	CW6.0
23	Ultrasound transducer	EVN4-9
24	Ultrasound transducer	PA4-12B
25	Ultrasound transducer	MMPT3-7
26	Ultrasound transducer	CA3-10A

NO	NAME OF DEVICE	IDENTIFIER
27	Ultrasound transducer	VR5-9
28	Ultrasound transducer	EA2-11AR
29	Ultrasound transducer	DP8B
30	Ultrasound transducer	EA2-11AV
31	Ultrasound transducer	EV2-10A
32	Ultrasound transducer	EVN4-8
33	Ultrasound transducer	LA3-16AD
34	Ultrasound transducer	CA2-8AD
35	Ultrasound transducer	PN2-4
36	Ultrasound transducer	VN4-8
37	Ultrasound transducer	LN5-12
38	Ultrasound transducer	L5-12/50
39	Ultrasound transducer	C2-5
40	Ultrasound transducer	C2-8
41	Ultrasound transducer	L4-7
42	Ultrasound transducer	LS6-15
43	Ultrasound transducer	SP3-8
44	Ultrasound transducer	CA4-10M
45	Ultrasound transducer	LA2-9S
46	Ultrasound transducer	PA3-9B
47	Ultrasound transducer	LA3-22AI
48	Ultrasound transducer	L3-22
49	Foot Switch	FSU-3000SM
50	Printer	P-95DE
51	Printer	P95DW
52	Printer	P59D

NO	NAME OF DEVICE	IDENTIFIER
53	Printer	UP-D897
54	Printer	UP-897MD
55	Printer	UP-X898MD
56	Printer	UP-D898MD
57	Printer	CP-30DW
58	Printer	UP-D25MD
59	Printer	CLP-620NDK
60	Printer	ML-2950



MEDICAL DEVICE AUTHORITY