





DEVICE DETAILS

NAME OF DEVICE	HS70A
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB3997822-105278
BRAND NAME	SAMSUNG
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	<p>The HS70A 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, M mode, Color Doppler imaging, Power Doppler imaging (including Directional Power Doppler mode; S-Flow), PW Spectral Doppler mode, CW Spectral Doppler mode, Harmonic imaging(S-Harmonic), Tissue Doppler imaging, Tissue Doppler Wave, 3D imaging mode (realtime 4D imaging mode), Elastoscan Mode or as a combination of these modes. The HS70A 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 HS70A has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed. The various transducers including linear array, curved linear array, endocavity, phased array and pencil array are available and any four (basic) or five (option) including one CW probe port may be connected at the same. 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. Customization includes transmit focusing, filtering, image enhancement processing, dynamic window curve selection. Controls are also provided to select display format (single and various combinations), to activate zoom features, and to utilize the cine loop function. The HS70A uses digital multi-beam forming technology, and supports a variety of Linear, Convex, Phased, Volume and CW probes for a wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions. Probes are supported in frequencies from 1.0 MHz to 20.0 MHz. These probes can be applied to a variety of clinical applications such as Fetal/Obstetrics (includes infertility monitoring of follicle development), Abdominal, Gynecology, Intra-operative, Pediatric, Small Organs, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.</p>
DEVICE INTENDED PURPOSE	<p>Ultrasound diagnostic system and probes were designed for obtaining ultrasound images and analyzing human blood. 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 and Peripheral vessel.</p>
VALIDITY DATE OF REGISTRATION	26/09/2022 - 25/09/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic Ultrasound Equipment	HS70A
2	Ultrasound transducer	L3-12A
3	Ultrasound transducer	LA3-16A
4	Ultrasound transducer	LA3-16AI
5	Ultrasound transducer	LA2-9A
6	Ultrasound transducer	LA4-18B
7	Ultrasound transducer	CA1-7A
8	Ultrasound transducer	CA2-8A
9	Ultrasound transducer	CF4-9
10	Ultrasound transducer	E3-12A
11	Ultrasound transducer	VR5-9
12	Ultrasound transducer 	EA2-11B
13	Ultrasound transducer	PA3-8B
14	Ultrasound transducer	PE2-4
15	Ultrasound transducer	CV1-8AD
16	Ultrasound transducer	LV3-14A
17	Ultrasound transducer	V5-9
18	Ultrasound transducer	DP2B
19	Ultrasound transducer	CA2-9A
20	Ultrasound transducer	CA3-10A
21	Ultrasound transducer	CW4.0
22	Ultrasound transducer	CW6.0
23	Ultrasound transducer	DP8B
24	Ultrasound transducer	MMPT3-7
25	Ultrasound transducer	PA1-5A

NO	NAME OF DEVICE	IDENTIFIER
26	Ultrasound transducer	PA4-12B
27	Ultrasound transducer	LM4-15B
28	Ultrasound transducer	EV2-10A
29	Foot switch	FSU-3000SM
30	Printer	P-95DE
31	Printer	P95DW
32	Printer	P59D
33	Printer	P95DE
34	Printer	UP-D897
35	Printer	UP-897MD
36	Printer	UP-X898MD
37	Printer	UP-D898MD
38	Printer 	CP-30DW
39	Printer	UP-D25MD