





DEVICE DETAILS

NAME OF DEVICE	DIAGNOSTIC ULTRASOUND APPARATUS V SERIES
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2572122-95534
BRAND NAME	SAMSUNG MEDISON CL., LTD
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The V8/V7/V6 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 (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode. The V8/V7/V6 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 V8/V7/V6 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.
DEVICE INTENDED PURPOSE	The ultrasound diagnostic system and probes are designed to obtain ultrasound images and analyze body fluid. 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.
VALIDITY DATE OF REGISTRATION	20/06/2022 - 19/06/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic Ultrasound Equipment	V8
2	Diagnostic Ultrasound Equipment	V7
3	Diagnostic Ultrasound Equipment	V6
4	Diagnostic Ultrasound Equipment	V5
5	Diagnostic Ultrasound Equipment	V4
6	Ultrasound transducer	LA2-14A
7	Ultrasound transducer	LA2-9A

NO	NAME OF DEVICE	IDENTIFIER
8	Ultrasound transducer	LA4-18A
9	Ultrasound transducer	LA3-22AI
10	Ultrasound transducer	CA1-7S
11	Ultrasound transducer	CA1-7SD
12	Ultrasound transducer	CA3-10A
13	Ultrasound transducer	CA4-10M
14	Ultrasound transducer	EA2-11AR
15	Ultrasound transducer	EA2-11AV
16	Ultrasound transducer	EA2-11ARD
17	Ultrasound transducer	EA2-11AVD
18	Ultrasound transducer	miniER7
19	Ultrasound transducer	EA2-11ARE
20	Ultrasound transducer 	EA2-11AVE
21	Ultrasound transducer	LA2-9S
22	Ultrasound transducer	LA3-14AD
23	Ultrasound transducer	LA4-18AD
24	Ultrasound transducer	PA1-5A
25	Ultrasound transducer	PA3-8B
26	Ultrasound transducer	PA4-12B
27	Ultrasound transducer	MMPT3-7
28	Ultrasound transducer	CV1-8A
29	Ultrasound transducer	EV2-10A
30	Ultrasound transducer	CV1-8AD
31	Ultrasound transducer	CV1-8AE
32	Ultrasound transducer	DP2B
33	Ultrasound transducer	CW6.0

NO	NAME OF DEVICE	IDENTIFIER
34	Ultrasound transducer	LM2-18
35	Ultrasound transducer	LA2-16S
36	Ultrasound transducer	L3-22
37	Ultrasound transducer	CA1-7AD
38	Ultrasound transducer	TA2-9
39	Ultrasound transducer	CA2-8AD
40	Ultrasound transducer	PA1-5AE
41	Ultrasound transducer	BCL2-14
42	Printer	UP-D897
43	Printer	UP-X898MD
44	Printer	UP-D898MD
45	Printer	UP-D25MD
46	Printer 	CLP-620NDK
47	Printer	ML-2950
48	Foot switch	FSU-3000 SM