

DEVICE DETAILS

NAME OF DEVICE	DIAGNOSTIC ULTRASOUND APPARATUS RS85 PRESTIGE, RS80 EVO
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB4792723-149386
BRAND NAME	SAMSUNG MEDISON CO., LTD
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The RS85 and RS80 EVO are general purpose, mobile, software controlled, ultrasound scanner. Its function is to acquire ultrasound data and to display the data as B-mode, M-mode, Pulsed wave (PW) Doppler, Continuous wave (CW) Doppler, Color Doppler, Tissue Doppler Imaging (TDI), Tissue Doppler Wave (TDW), Power Amplitude Doppler, Pulse Inversion Harmonic Imaging (S-Harmonic), Directional Power Doppler (S-Flow), Color M-Mode, 3D Imaging Mode, 4D Imaging Mode, ElastoScan+ Mode, Tissue Harmonic Imaging, MV-Flow Mode or as a combination of these modes. The RS85 and RS80 EVO 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 RS85 and RS80 EVO have 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 fluids. The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Intraoperative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal(Cardiac), Ophthalmic, and Peripheral vessel. It is intended for use by, or by the order of, and under the supervision of, an appropriately trained healthcare professional who is qualified for direct use of medical devices. It can be used in hospitals, private practices, clinics and similar care environment for clinical diagnosis of patients
VALIDITY DATE OF REGISTRATION	27/09/2023 - 26/09/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic Ultrasound Equipment	RS85
2	Diagnostic Ultrasound Equipment	RS80 EVO

NO	NAME OF DEVICE	IDENTIFIER
3	Ultrasound transducer	L3-12A
4	Ultrasound transducer	LA2-9A
5	Ultrasound transducer	LA2-9S
6	Ultrasound transducer	LA2-14A
7	Ultrasound transducer	LA3-16A
8	Ultrasound transducer	LA3-16AI
9	Ultrasound transducer	LA3-22AI
10	Ultrasound transducer	LA4-18A
11	Ultrasound transducer	LA4-18B
12	Ultrasound transducer	LM2-18
13	Ultrasound transducer	LM4-15B
14	Ultrasound transducer	CA1-7A
15	Ultrasound transducer	CA1-7S
16	Ultrasound transducer	CA2-8A
17	Ultrasound transducer	CF4-9
18	Ultrasound transducer	CA3-10A
19	Ultrasound transducer	CA4-10M
20	Ultrasound transducer	E3-12A
21	Ultrasound transducer	EA2-11B
22	Ultrasound transducer	EA2-11AR
23	Ultrasound transducer	EA2-11AV
24	Ultrasound transducer	MMPT3-7
25	Ultrasound transducer	V5-9
26	Ultrasound transducer	LV3-14A
27	Ultrasound transducer	CV1-8A
28	Ultrasound transducer	EV2-10A

NO	NAME OF DEVICE	IDENTIFIER
29	Ultrasound transducer	EV3-10B
30	Ultrasound transducer	PA1-5A
31	Ultrasound transducer	PA3-8B
32	Ultrasound transducer	PA4-12B
33	Ultrasound transducer	PM1-6A
34	Ultrasound transducer	CW6.0
35	Ultrasound transducer	DP2B
36	Ultrasound transducer	DP8B
37	Ultrasound transducer	miniER7
38	Ultrasound transducer	L3-22



MEDICAL DEVICE AUTHORITY