



DEVICE DETAILS

NAME OF DEVICE	RS80 EVO DIAGNOSTIC ULTRASOUND APPARATUS
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2546820-44896
BRAND NAME	SAMSUNG MEDISON CO., LTD
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	<p>The RS80 EVO 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, Tissue Doppler imaging, Tissue Doppler Wave, 3D imaging mode (real-time 4D imaging mode), Elastoscans+ Mode or as a combination of these modes. The RS80 EVO also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that may aid in making a diagnosis by competent health care professionals. The RS80 EVO has 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	<p>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, Tissue Doppler imaging, Tissue Doppler Wave, 3D imaging mode (real-time 4D imaging mode), Elastoscans+ Mode or as a combination of these modes. The RS80 EVO also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that may aid in making a diagnosis by competent health care professionals.</p>
VALIDITY DATE OF REGISTRATION	08/07/2020 - 07/07/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic Ultrasound Equipment	RS80 EVO
2	Ultrasound transducer	CA1-7A
3	Ultrasound transducer	E3-12A
4	Ultrasound transducer	CF4-9

NO	NAME OF DEVICE	IDENTIFIER
5	Ultrasound transducer	CA2-8A
6	Ultrasound transducer	CA3-10A
7	Ultrasound transducer	EV3-10B
8	Ultrasound transducer	LV3-14A
9	Ultrasound transducer	V5-9
10	Ultrasound transducer	CV1-8A
11	Ultrasound transducer	LA3-16AI
12	Ultrasound transducer	L3-12A
13	Ultrasound transducer	LA3-16A
14	Ultrasound transducer	LA2-9A
15	Ultrasound transducer	LA4-18B
16	Ultrasound transducer 	PM1-6A
17	Ultrasound transducer	PA3-8B
18	Ultrasound transducer MEDICAL DEVICE AUTHORITY	PA4-12B
19	Ultrasound transducer	CW6.0
20	Ultrasound transducer	DP2B
21	Ultrasound transducer	MMPT3-7
22	Ultrasound transducer	EA2-11B
23	Ultrasound transducer	DP8B