




DEVICE DETAILS

NAME OF DEVICE	HERA W9, HERA W10 DIAGNOSTIC ULTRASOUND APPARATUS
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB7667124-171413
BRAND NAME	SAMSUNG MEDISON CO., LTD
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The HERA W9, HERA W10 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 HERA W9, HERA W10 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 HERA W9, HERA W10 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, Thoracic, Trans-esophageal (Cardiac) and Peripheral vessel.
VALIDITY DATE OF REGISTRATION	28/04/2024 - 27/04/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic Ultrasound Equipment	HERA W9
2	Diagnostic Ultrasound Equipment	HERA W10
3	Ultrasound transducer	CA1-7A
4	Ultrasound transducer	CA2-9A
5	Ultrasound transducer	CA3-10A
6	Ultrasound transducer	EA2-11B

NO	NAME OF DEVICE	IDENTIFIER
7	Ultrasound transducer	VR5-9
8	Ultrasound transducer	E3-12A
9	Ultrasound transducer	CF4-9
10	Ultrasound transducer	EV3-10B
11	Ultrasound transducer	CV1-8A
12	Ultrasound transducer	L3-12A
13	Ultrasound transducer	LA2-9A
14	Ultrasound transducer	LA4-18B
15	Ultrasound transducer	PM1-6A
16	Ultrasound transducer	PA3-8B
17	Ultrasound transducer	PA4-12B
18	Ultrasound transducer	EA2-11AR
19	Ultrasound transducer 	EA2-11AV
20	Ultrasound transducer	EV2-10A
21	Ultrasound transducer	LA2-14A
22	Ultrasound transducer	PA1-5A
23	Ultrasound transducer	EV2-12
24	Foot Switch	FSU-3000SM
25	Printer	UP-D897
26	Printer	ML-2955DW
27	Printer	UP-X898MD
28	Printer	UP-D898MD
29	Printer	CLP-615ND
30	Printer	UP-D25MD