



DEVICE DETAILS

NAME OF DEVICE	HERA W9 DIAGNOSTIC ULTRASOUND APPARATUS
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2791320-44450
BRAND NAME	HERA W9 - SAMSUNG MEDISON
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	<p>The HERA W9 is 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, 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, Elastocan+ Mode, Tissue Harmonic Imaging, MV-Flow Mode or as a combination of these modes. The HERA W10 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 HERA W9 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>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.</p>
VALIDITY DATE OF REGISTRATION	24/06/2020 - 23/06/2025

LIST OF DEVICE

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

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