

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	
No results found.			