




DEVICE DETAILS

NAME OF DEVICE	HERA Z20, HERA Z30, R20, R30 DIAGNOSTIC ULTRASOUND APPARATUS
ESTABLISHMENT NAME	LAC MEDICAL SUPPLIES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB5739224-190814
BRAND NAME	SAMSUNG MEDISON CO.,LTD.,R.O.KOREA
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The HERA Z20 is a 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 HERA Z20 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 Z20 has real time acoustic output display with two basic indices, a mechanical index and a thermal
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, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac) and Peripheral vessel.
VALIDITY DATE OF REGISTRATION	25/11/2024 - 24/11/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Ultrasound transducer	LM2-18
2	Ultrasound transducer	LA3-22AI
3	Ultrasound transducer	CA1-7S
4	Ultrasound transducer	CA3-10A
5	Ultrasound transducer	PA1-5A
6	Ultrasound transducer	EA2-11AR
7	Ultrasound transducer	EA2-11AV

NO	NAME OF DEVICE	IDENTIFIER
8	Ultrasound transducer	CMV1-10
9	Ultrasound transducer	CV1-8A
10	Ultrasound transducer	EV2-12
11	Printer	UP-D897
12	Printer	UP-D25MD
13	Printer	CLP-620NDK
14	Printer	ML-2950
15	Foot switch	FSU-3000 SM
16	Diagnostic Ultrasound Equipment	HERA Z20
17	Diagnostic Ultrasound Equipment	R20
18	Diagnostic Ultrasound Equipment	R30
19	Diagnostic Ultrasound Equipment	HERA Z30
20	Ultrasound transducer 	CMV1-10Z
21	Ultrasound transducer	L3-22
22	Ultrasound transducer	LA2-9S
23	Ultrasound transducer	LA2-14A
24	Ultrasound transducer	LA2-16S
25	Ultrasound transducer	LM2-18
26	Ultrasound transducer	LA3-22AI
27	Ultrasound transducer	CA1-7S
28	Ultrasound transducer	CA3-10A
29	Ultrasound transducer	PA1-5A
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31	Ultrasound transducer	EA2-11AV
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33	Ultrasound transducer	CV1-8A

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