

DEVICE DETAILS

NAME OF DEVICE	U60 DIAGNOSTIC ULTRASOUND SYSTEM
ESTABLISHMENT NAME	ROCKY SCIENTIFIC INSTRUMENTATION
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2604323-117884
BRAND NAME	EDAN
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	The U60 is a portable Diagnostic Ultrasound System, which applies advanced technologies such as Phased Inversion Harmonic Compound Imaging (eHCI), Multi-Beam-Forming (mBeam), Speckle Resistance Imaging (eSRI), and Spatial Compounding Imaging, etc. Various image parameter adjustments, 15-inch LCD and diverse probes are configured to provide clear and stable images. The device is not incorporated medicinal substances, tissues or blood products. The device consists of a main unit and accessories, including transducers, needle guide brackets, ECG cable, etc. The diagnostic ultrasound system (U50/U60/U2) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), endovaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.
DEVICE INTENDED PURPOSE	The diagnostic ultrasound system (U60) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), endovaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.
VALIDITY DATE OF REGISTRATION	03/02/2023 - 02/02/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Diagnostic Ultrasound System	U60
2	Potential Equalization Conductor	01.13.114214
3	Power Cord (UK. Standard,10A)	01.13.036641
4	Flash Disk (Netac,4G, USB2.0 Protocol)	01.18.052245

NO	NAME OF DEVICE	IDENTIFIER
5	Ultrasound Gel(CE Mark, 250g)[*CE+CA+BA*]	01.57.078008
6	Quick Manuel for U60 (English)	01.54.457983
7	User Manuel for U60 (English)	01.54.457919
8	Convex array transducer: C352UB(2.5/3.5/4.5/H5.0/H5.4MHz, 128 elements)[*CE+FDA+CA*]	02.01.214369
9	Linear array transducer: L742UB(6.5/7.5/8.5/H9.0/H 9.4MHz, 128 elements)	02.01.214370
10	Linear array transducer: L1042UB(8/9.5/11/H13.0/ H 13.4MHz, 128 elements)	02.01.214382
11	Transvaginal array transducer: E612UB(5.5/6.5/7.5/H9.0 / H9.4MHz, 128 elements)	02.01.214381
12	Linear array transducer: L15-7b(10.0/12.0/14.0/H14.4/H14.8MHz, 128 elements)	02.01.214388
13	Micro-convex array transducer C6152UB(5.5/6.5/7.5/H9.0/H9.4MHz,128 elements)	02.01.214384
14	Micro-convex array transducer : C612UB (5.5/6.5/7.5/H9.0/ H9.4MHz,128 elements)	02.01.214383
15	Linear array transducer: L552UB((4.5/5.5/6.5/H5.6/H6.0MHz, 128 elements)	02.01.214386
16	Micro-convex array transducer: C422UB(3.0/4.0/5.0/H5.0/ H5.4MHz,128 elements)	02.01.214385
17	Convex array transducer: C5-2b(2.5/3.5/4.0/H5.0/H6.0MHz, 128 elements)	02.01.214387
18	Phase array transducer: P5-1b(2.0/2.5/3.0/H4.0/H5.0MHz, 64 elements)	02.01.214389
19	BGK-C5-2 for C5-2b/C5-2D/C5-2Q	02.01.211006012
20	BGK-CR10UA For E8-4Q	02.01.102963013
21	BGK-L40UB for L12-5Q/ L17-7HQ/ L742UB/ L1042UB/ L15-7b (In-Plane)	02.01.210407013
22	BGK-L50UB for L552UB	02.01.210620011
23	BGK-R10UB for C612UB	02.01.210617012
24	BGK-R15UB for C6152UB/MC8-4Q/MC8-4D	02.01.210618013
25	BGK-R20UB for C422UB	02.01.210619012
26	Needle Guide Bracket for convex transducer C352UB, BGK-R50UB	02.01.210406-11
27	Color UP-D25MD,423 DPI,AC100~240V,50/60Hz,USB 2.0	01.18.052511

NO	NAME OF DEVICE	IDENTIFIER
28	Color UP-25MD,423 DPI,AC100~240V,50/60Hz,S-Video/Video, UPC-21S	01.18.052512
29	Video printer paper for UP-898MD (SONY, UPP-110S, 110mm×20m)	11.57.78017
30	Video printer paper for UP-898MD (SONY, UPP-110HG, 110mm×18m)	11.57.471109
31	Video printer paper for SONY UP-D25MD (SONY UPC-21L?L size?200 pcs)	11.57.471277
32	Video printer paper for SONY,UP-25MD(SONY,UPC-21S?S size?240 pcs)	11.57.471207
33	KP61B-CE,110mmX20m,CE conformity, 4 roll/Box	01.57.471033
34	Luxury Mobile Trolley, Chinese label and English label	83.63.560583
35	Parker Ultrasound Gel(CE&FDA Mark, 250g)[*FDA Only*]	01.57.078001
36	Luxury carrying bag	01.56.466571
37	Flash Disk (Netac,4G, USB2.0 Protocol)	01.18.052245
38	Foot switch	21.10.027169
39	USB DVD RW	01.17.102580
40	DICOM software package	02.05.250683-10
41	Rechargeable Lithium-Ion Battery (14.8V, 5000mAh)	01.21.064143
42	UMS100 software package	83.63.326001
43	Dust Cover	01.57.471026
44	U60 service manual	01.54.457969