

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN



MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GC7782620-43369**
Registration No.:

Tarikh Sah Pendaftaran: **23/05/2020 - 22/05/2025**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada:
This certificate is hereby issued to:

H&A MEDICAL SUPPLY SDN BHD

yang beralamat di:
which is located at:

**CT-05-11 CORPORATE TOWER SUBANG
SQUARE JALAN SS15/4G, SUBANG JAYA,
47500
SELANGOR DARUL EHSAN**

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.



AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
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No. Pendaftaran: **GC7782620-43369**

Registration No.:

Butir-butir peranti perubatan yang didaftarkan

Particulars of the registered medical device

Nama Peranti Perubatan **RESPIRATORY GATING SYSTEM AZ-733VI**

Medical Device Name

Kelas
Class

CLASS C

Jenama
Brand

AZ-733VI

Kelompok
Group

SYSTEM

Nama dan alamat
pembuat:
Name and address of
manufacturer

ANZAI MEDICAL CO., LTD
3-6-25 NISHI-SHINAGAWA, SHINAGAWA-KU TOKYO, JAPAN,
3-6-25
JAPAN

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Sensor Port	400322-1	Standard Components
2	Relay Box	400322-2	Standard Components
3	Gate Disable Switch	400322-3	Standard Components
4	Personal Computer with Mouse	400322-4	Standard Components
5	Load Cell Standard Type	400322-5	Standard Components
6	Load Cell Deep Type	400322-6	Standard Components
7	Loadcell Fixing Belt (S)	400073-8	Standard Components
8	Loadcell Fixing Belt (M)	400073-7	Standard Components
9	Loadcell Fixing Belt (L)	400073-6	Standard Components
10	Loadcell Fixing Belt (LL)	400073-36	Standard Components
11	Loadcell Calibrator	400073-9	Standard Components
12	Load Cell Calibrator	400073-9	Standard Components
13	SP-RB I/O Cable (Sensor Port - Relay Box)	400322-18	Standard Components
14	GDS Cable (Relay Box - Gate Disable Switch)	400322-19	Standard Components
15	Sensor Cable (Sensor Port - Load Cell or Laser Sensor)	400322-20	Standard Components
16	USB Cable (Relay Box - Personal Computer)	400322-21	Standard Components



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
17	EXT.I/O Cable (SP, RB - Exterior Device.)	400322-38	Standard Components
18	AC Power Cable (For USA)	400073-43	Standard Components
19	AC Power Cable (For EU)	400073-14	Standard Components
20	User's Manual	400322-30	Standard Components
21	Screwdriver Set	400073-22	Standard Components
22	Laser Sensor (85mm)	400322-11	Option
23	Laser Sensor (120mm)	400322-12	Option
24	Laser Sensor (250mm)	400322-49	Option
25	Laser Sensor Fixture (Type A)	400074-1	Option
26	Laser Sensor Fixture (Type M)	400074-13	Option
27	Laser Sensor Fixture (Type T)	400074-4	Option
28	Wave Monitor [WM]	400322-14	Option
29	ECG Board	400322-15	Option
30	Interface Board 1	400322-16	Option
31	Interface Board 2	400322-17	Option
32	Wave Monitor Cable (Sensor Port - Wave Monitor)	400322-27	Option
33	ECG Cable (Sensor Port - ECG)	400322-39	Option
34	RS232C Cable (Sensor Port - Exterior Device)	400322-40	Option
35	Interface Board 3	400322-34	Option
36	Connection Box	400322-33	Option
37	Connection Box Cable (Relay Box - Connection Box)	400322-35	Option
38	Reflector	400322-52	Option
39	IRP Sensor Main Unit	400322-51	Option
40	IRP Sensor Fixture(Type T)	400322-54	Option
"End Of Product List"			