No. Siri: 019143
Serial No.:

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: **GMD95099689818A**
Registration No.:

Tarikh Sah Laku Pendaftaran: **26/06/2018 - 25/06/2023**
Registration Validity Date:

Sijil ini adalah dengan ini dikeluarkan kepada:
This Certificate is hereby issued to:

UNITED AKRAB TECH SDN BHD

yang beralamat di:
of:

LOT 1, LORONG 19 / 1A
PETALING JAYA.
46300 SELANGOR

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.

ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
Pihak Berkuasa Peranti Perubatan
Medical Device Authority

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GMD95099689818A**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**FUNCTIONAL TESTING DEVICES**		
Kelas *Class*	**CLASS A**	Brand *Brand*	**JTECH**
Kelompok *Group*	**SET**		
Kegunaan Yang Diniatkan *Intended Use*	**To assist the clinician with establishing an objective assessment of a person's physical strength, range of movement, and establishing pain tolerance levels. The devices are intended to be used as non-invasive, non-surgical, transient devices.**		
Nama dan alamat pembuat: *Name and address of manufacturer*	**JTECH MEDICAL INDUSTRIES, INC 7633 S MAIN MIDVALE UTAH**		

APPENDIX

No.	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1.	Northstar Echo Primary Inclinometer	9RF403	Device for measuring range of motion
2.	Echo Primary Inclinometer	9RF303	Device for measuring range of motion
3.	Echo Secondary Inclinometer	9RF304	Device for measuring range of motion
4.	Echo Muscle Tester	9RF305	Device for measuring muscle strength
5.	Echo Grip Gauge	9RF306	Device for measuring hand grip strength
6.	Echo Algometer	9RF307	Device for measuring pressure sensitivity
7.	Echo Goniometer	9RF308	Device for measuring range of motion
8.	Echo Pinch Gauge	9RF309	Device for measuring pinch strength
9.	Echo Static Force Gauge	9RF310	Device for measuring lift, push, and pull capability
10.	Echo Basic Receiver	RF117	Used to transfer signal from Echo devices to computer software (Tracker 5, IRIS, Northstar)
11.	Commander Echo Console	9RF316	Used to get signal from Echo devices and present in readable format without computer
12.	Northstar Echo Receiver	9RF401	Used to transfer signal from Norhtstar Echo devices to computer software (Tracker 5, IRIS, Northstar)
13.	Northstar Echo Secondary Inclinometer	9RF404	Device for measuring range of motion
14.	Northsar Echo Muscle Tester	9RF405	Device for measuring muscle strength
15.	Northstar Echo Grip Gauge	9RF406	Device for measuring hand grip strength
16.	Northstar Echo Algometer	9RF407	Device for measuring pressure sensitivity
17.	Northstar Echo Goniometer	9RF408	Device for measuring range of motion
18.	Northstar Echo Pinch Gauge	9RF409	Device for measuring pinch strength
19.	Northstar Echo Static Force Gauge	9RF410	Device for measuring lift, push, and pull capability
20.	Northstar Echo Test End Switch	RF116	Device for signaling end of algometry test
21.	Commander Muscle Tester	AA 104	Device for measuring muscle strength
22.	Commander Grip	AA 105	Device for measuring hand grip strength
23.	Commander Pinch	AA 106	Device for measuring pinch strength
24.	Commander Algometer	AA 129	Device for measuring pressure sensitivity
25.	Downloader	AA 119	Device allowing Commander to connect to computer to download information
26.	Dualer IQ Pro Primary	9CM113	Device for measuring range of motion
27.	Dualer IQ Pro Secondary	9CM114	Device for measuring range of motion

28.	Tracker Freedom Wireless Receiver	9RF001	Used to transfer signal from Tracker Freedom devices to computer software (Tracker 5, IRIS, Northstar)
29.	Tracker Freedom Wireless Foot Switch	9RF102	Device for signaling end of range of motion tests
30.	Tracker Freedom Wireless Primary Inclinometer	9RF103	Device for measuring range of motion
31.	Tracker Freedom Wireless Secondary Inclinometer	9RF104	Device for measuring range of motion
32.	Tracker Freedom Wireless Muscle Tester	9RF105	Device for measuring muscle strength
33.	Tracker Freedom Wireless Grip	9RF106	Device for measuring hand grip strength
34.	Tracker Freedom Wireless Algometer	9RF107	Device for measuring pressure sensitivity
35.	Tracker Freedom Wireless Goniometer	9RF108	Device for measuring range of motion
36.	Tracker Freedom Wireless Pinch	9RF109	Device for measuring pinch strength
37.	Tracker Freedom Wireless Static Force Gauge	9RF110A	Device for measuring lift, push, and pull capability
38.	Tracker Freedom Wireless Algometry End-Test Switch	9RF115	Device for signaling end of algometry test
39.	Tracker 5	DM021	Software for displaying readable data from Echo and Tracker Freedom devices on a computer
40.	Northstar	DM016	Software for displaying readable data from Echo and Tracker Freedom devices on a computer
41.	Commander Echo Downloader	DM023	Software for exporting data from Commander Echo console to basic report
42.	IRIS	DM024	Software for capturing data from Tracker Freedom, Echo, and Northstar Echo devices and displaying basic information or allowing user to create their own interface
43.	Commander Downloader Software	DM010	Software for exporting data from Commander devices to basic report using Commander Downloader

SYARAT – SYARAT PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CONDITIONS

1.0 SYARAT AM
GENERAL CONDITIONS

1.1 Syarat-syarat pendaftaran peranti perubatan ini dibuat adalah berdasarkan kepada Seksyen 7 (1), Akta Peranti Perubatan 2012 (Akta 737). Kelulusan ini diberi berdasarkan maklumat-maklumat yang telah diterima.
Medical device registration conditions are prescribed in accordance to Section 7(1) of Medical Device Act (Act 737). Approval is granted based on information received.

1.2 Establismen hendaklah mematuhi segala arahan yang dikeluarkan oleh Pihak Berkuasa dari semasa ke semasa.
Establishment must comply with all instructions issued by the Authority from time to time.

1.3 Pihak Berkuasa berhak untuk meminda syarat-syarat pendaftaran dari semasa ke semasa.
The Authority reserves the rights to amend the registration conditions from time to time.

1.4 Pihak Berkuasa berhak untuk membuat lawatan atau pemeriksaan ke atas establismen pada bila-bila masa tanpa dimaklumkan terlebih dahulu.
The Authority reserves the right to conduct visit or inspection at any time without prior notice.

1.5 Pihak Berkuasa boleh membatalkan Pendaftaran Peranti Perubatan atau mengambil tindakan undang-undang sekiranya Establismen gagal mematuhi mana-mana syarat Pendaftaran Peranti Perubatan.
The Authority may cancel the Medical Device Registration or take legal action if the Establishment fails to comply with any medical device registration conditions.

1.6 Sijil Pendaftaran Peranti Perubatan yang dikeluarkan oleh Pihak Berkuasa tidak boleh dipindah milik.
Medical Device Registration Certificate issued by the Authority shall not be transferable or assignable.

1.7 Sijil Pendaftaran Peranti Perubatan hendaklah dikemukakan sekiranya diminta oleh mana-mana pegawai yang diberi kuasa.
Medical Device Registration Certificate must be presented upon request by any authorized officer.

1.8 Establismen tidak boleh membenarkan Sijil Pendaftaran Peranti Perubatan disalahgunakan oleh individu/syarikat lain dalam apa-apa cara.
Establishment shall not permit the Medical Device Registration Certificate to be abused in any way by any individual / another party.

1.9 Tempoh sahlaku Sijil Pendaftaran Peranti Perubatan adalah lima (5) tahun dari tarikh pendaftaran melainkan jika pendaftaran itu dibatalkan oleh Pihak Berkuasa sebelum habis tempohnya.
The validity of the Medical Device Registration Certificate is five (5) years from the date of registration unless the registration is cancelled by the Authority before its expiry.

1.10 Pengiklanan peranti perubatan hendaklah tidak mengandungi apa-apa kenyataan yang boleh membawa maksud, sama ada secara langsung atau tidak langsung bahawa penggunaan peranti perubatan adalah dicadangkan, dipromosikan atau disahkan oleh Pihak Berkuasa atau mana-mana pihak yang berkaitan.
Advertising of medical device shall not contain any statement, whether directly or indirectly that the use of that medical device is suggested, promoted or endorsed by the Authority or another related party.

4.0 HAK PIHAK BERKUASA
THE AUTHORITY OWNERSHIP

4.1 Sijil Pendaftaran Peranti Perubatan yang dikeluarkan secara manual atau elektronik adalah **Hak Milik Pihak Berkuasa**.
The Authority retains the ownership of every Medical Device Registration Certificate issued by any means.

4.2 Sekiranya berlaku kehilangan atau kerosakan Sijil Pendaftaran Peranti Perubatan, hendaklah dimaklumkan kepada Pihak Berkuasa dan setiap penggantian sijil akan dikenakan caj perkhidmatan.
Any loss or damage to the Medical Device Registration Certificate shall be notified to the Authority and every replacement of certificate shall be liable with service charge rendered.

5.0 TUGAS DAN TANGGUNGJAWAB
ROLES AND RESPONSIBILITIES

5.1 Establismen hendaklah mematuhi Akta 737, peraturan-peraturan di bawah Akta dan syarat-syarat Pendaftaran Peranti Perubatan.
Establishment shall comply with Act 737, its subsidiary regulations and registration conditions.

1.11 Tujuan yang diniatkan bagi peranti perubatan hendaklah dinyatakan dengan jelas dalam iklan produk, termasuk brosur, risalah dan lain-lain, dan tidak boleh merujuk kepada mana-mana 20 jenis penyakit yang tidak boleh diiklankan seperti yang tertakluk kepada Seksyen 3(1) Akta Ubat (Iklan Dan Penjualan) 1956.
Intended purpose of medical device shall be clearly stated in the advertisement of products, including brochures, pamphlets, and etc., and shall not refer to any 20 types of diseases that cannot be advertised as prescribed in Section 3 (1) of the Medicines (Advertisement and Sale) Act 1956.

1.12 Ia adalah menjadi tanggungjawab Establishmen untuk memastikan peranti perubatan mematuhi mana-mana keperluan undang-undang lain yang berkaitan. Sijil ini tidak mengecualikan mana-mana keperluan peraturan yang terpakai untuk peranti perubatan tersebut. (contoh: Peranti Perubatan yang mengandungi racun berjadual tertakluk kepada Akta Racun 1952; peranti perubatan menggunakan sinaran mengion adalah tertakluk kepada Akta Perlesenan Tenaga Atom 1984.)
It is the responsibility of the Establishment to ensure that medical device complies with any other requirements of the law. This certificate does not exclude any regulatory requirements applicable to medical device (for examples: Medical Device containing scheduled poison is subjected to the Poisons Act 1952; medical devices using ionizing radiation is subjected to the Atomic Energy Licensing Act 1984) .

1.13 Establismen hendaklah melaporkan insiden melibatkan peranti perubatan yang didaftarkan kepada Pihak Berkuasa seperti tertakluk di bawah Seksyen 40 Akta 737.
Establishment shall report any incidents involving registered medical device to the Authority as prescribed in Section 40 of Act 737.

1.14 Peranti perubatan yang diniatkan bagi kegunaan professional hanya boleh dibekalkan untuk kegunaan professional perubatan sahaja dan tidak boleh diletakkan dipasaran bagi kegunaan orang awam.
Medical device intended for professional use may only be supplied for use by medical professionals only and shall not be placed in the market for general public.

2.0 PINDAAN PENDAFTARAN PERANTI PERUBATAN
AMENDMENT OF MEDICAL DEVICE REGISTRATION

2.1 Sebarang pindaan kepada maklumat yang berkaitan peranti perubatan yang berdaftar hendaklah dimaklumkan kepada Pihak Berkuasa secara rasmi mengikut garis panduan yang ditetapkan oleh Pihak Berkuasa. Pihak Berkuasa berhak memberikan kelulusan atau menolak permohonan pindaan tersebut.
Any amendments to the information concerning registered medical device shall be notified to the Authority in accordance to the guidelines set by the Authority. The Authority reserves the right to grant approval or reject the application for such amendments.

3.0 PEMBATALAN SIJIL PENDAFTARAN PERANTI PERUBATAN
CANCELLATION OF MEDICAL DEVICE REGISTRATION CERTIFICATE

3.1 Sijil Pendaftaran Peranti Perubatan boleh dibatalkan seperti yang dinyatakan dalam Seksyen 9, Akta 737.
Medical Device Registration may be cancelled as prescribed in Section 9 of Act 737.

3.2 Mana-mana peranti perubatan yang dibatalkan Sijil Pendaftarannya, tidak boleh diimport, dieksport atau diletakkan dalam pasaran.
Any Medical Device which the registration certificate has been cancelled shall not be imported, exported or placed in the market.