No. Siri:
Serial No.: 042676

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: **GB633911301219**
Registration No.:

Tarikh Sah Pendaftaran: **14/02/2019 - 13/02/2024**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **ANDAMAN MEDICAL BRIDGE SDN. BHD.**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

UNIT 3.3A, 3RD FLOOR WISMA LEADER, NO.8
JALAN LARUT, ,
10050
PULAU PINANG PULAU PINANG PULAU
MUTIARA

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
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GB633911301219**
Registration No.:

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

Nama Peranti Perubatan **RESTORATIVE THERAPIES RT600 FES STEPPER ERGOMETER**
Medical Device Name

Kelas *Class*	**CLASS B**	Jenama *Brand*	**RESTORATIVE THERAPIES**
Kelompok *Group*	**FAMILY**		
Nama dan alamat pembuat: *Name and address of manufacturer*	**RESTORATIVE THERAPIES, INC, 907 SOUTH LAKEWOOD AVE, BALTIMORE, MARYLAND 21224 , 21224 UNITED STATES**		

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	RT 300-SL Home	FA 100052	FES motorized Leg Ergometer
2	RT-300 SLSA	FA 104 581 Home	FES motorized Leg and Arm Ergometer
3	RT300-SA Home	FA 109064	FES motorized Arm Ergometer
4	RT 300 UE Upgrade Home	FA 105419 Home	Additional Upper Extremity Upgrade
5	RT 300-SLA Home	FA 102011	FES on One Side Leg or Arm
6	RT 300 Supine	FA 211372 Supine	Stimulate one or both legs and trunk while you cycle from a supine position
7	RT-200 SLSA Home	FA 109136	Has a continuos and smooth elliptical motion and stimulate arms and legs together.
8	RT-200 SA Home	FA 211762	Stimulates Arm
9	RT50 wireless stimulators	SA216128	Single channel nerve stimulators that expand system up to 10 channels to stimulate more muscle groups
10	RT600 Home System	FA 211509	fully integrated upright FES Therapy System

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
11	SAGE FES Control System	SAGE controller	Smart stimulation therapy system with large color touch sensitive display that features big and easy to operate buttons that delivers comprehensive FES therapy and provides essential feedback via Internet.
12	Universal Stimulation Cables	PP216520	Standard Accessory
13	Set of Arm and Leg Electrodes	PP100416 - 3"x4" PP100015 - 2"x3.5" PP100418 - 2"x2"	Standard Accessory
14	RT 600 Hoist Assembly	FA 213565	Hoist Assembly
15	Harness Adult	PP213567	Harness
16	Harness Paediatric	PP 213568	Harness
17	UE Ergometer Series 2	SA 110368	Ergometer
18	LE Ergometer Series 2	SA 110267	Ergometer
		"End Of Product List"	

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.

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.

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.

PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
ARAS 6, PRIMA 9, PRIMA AVENUE II, BLOCK 3547
PERSIARAN APEC, 63000 CYBERJAYA.
TEL : (+603)8230 0300

Ref : MDR-20211217-41686
Date : 04-03-2022

To whom it may concern,

Dear Sir/Madam,

CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (CATEGORY 3)

The above matter is referred.

Please be informed that your change notification request for the medical device as follows has been approved.

Establishment Name	: **ANDAMAN MEDICAL BRIDGE SDN. BHD.**
Medical Device Registration Certificate No.	: GB633911301219
Medical Device Name	: RESTORATIVE THERAPIES RT600 FES STEPPER ERGOMETER
Description of Change	: **Refer Attachment of Approval**

2. This change notification shall be attached together with the medical device registration certificate. The validity of this document shall follow the date as stated in the medical device registration certificate.

Thank you,

AHMAD SHARIFF BIN HAMBALI
CHIEF EXECUTIVE
Medical Device Authority,
Ministry of Health Malaysia.

Ref : MDR-20211217-41686
Date : 04-03-2022

Attachment of Approval

Change Notification for Category 3

TYPE OF CHANGE(S)	DESCRIPTION OF CHANGE(S)
5.6.1 Change in manufacturing facility, process and quality management system (QMS)	
(a) All changes to certificates for manufacturing and sterilisation facilities that: i) involves an update of certificate QMS validity date only OR; ii) change in scope of the QMS certification which affect the registered medical device (that is not due to safety, and/or performance of the medical device) OR; iii) involves a cancellation of QMS scope on the certificate for any of the multiple existing manufacturing facilities that is related to the registered medical device (that is not due to safety, and/or performance of the medical device), OR; iv) involves the change in conformity assessment body with no change in scope of the certification OR; v) involves the expansion of scope of the QMS certification which does not affect the registered medical device.	Information has been updated in technical documents
5.6.3 Changes to labelling of medical devices	
(c) Other labelling changes involving information in the labelling that does not fall under above (a) and (b). Rephrasing information/ Change in arrangement in IFU/ Change of colour/ font size/ location of information/ correction of spelling mistake or any administrative change (e.g. from Rd. to road), for example, do not required change notification	Information has been updated in technical documents
5.6.4 Changes to registered medical devices registration information	
(b) All deletions of a medical device from medical device registration (for medical devices in grouping).	Please refer to the updated List of Configuration

TYPE OF CHANGE(S)	DESCRIPTION OF CHANGE(S)
(c) All changes in the manufacturer information that only: i) involve changes in manufacturer’s name and address OR; ii) involve changes in the manufacturing site's name only, with no changes in the manufacturing site’s address.	**MANUFACTURER INFORMATION** RESTORATIVE THERAPIES, INC, 1434 FLEET , STREET, BALTIMORE, MARYLAND 21231, UNITED STATES. 21231 UNITED STATES **MANUFACTURING SITE**

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GB633911301219**
Registration No.:

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

Nama Peranti Perubatan **RESTORATIVE THERAPIES RT600 FES STEPPER ERGOMETER**
Medical Device Name

Kelas **CLASS B** Jenama **RESTORATIVE THERAPIES**
Class *Brand*

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **RESTORATIVE THERAPIES, INC, 1434 FLEET , STREET, BALTIMORE, MARYLAND 21231, UNITED STATES. , 21231 UNITED STATES**
Name and address of manufacturer

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	RT 300-SL Home	FA 100052	FES motorized Leg Ergometer
2	RT-300 SLSA	FA 104 581 Home	FES motorized Leg and Arm Ergometer
3	RT 300 UE Upgrade Home	FA 105419 Home	Additional Upper Extremity Upgrade
4	RT 300-SLA Home	FA 102011	FES on One Side Leg or Arm
"End Of Product List"			

No. Siri:
Serial No.: 047550

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: **GB2187522-93304**
Registration No.:

Tarikh Sah Pendaftaran: **18/05/2022 - 17/05/2027**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **ANDAMAN MEDICAL BRIDGE SDN. BHD.**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

UNIT 3.3A, 3RD FLOOR WISMA LEADER, NO.8
JALAN LARUT, ,
10050
PULAU PINANG PULAU PINANG PULAU
MUTIARA

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
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GB2187522-93304**
Registration No.:

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

Nama Peranti Perubatan **XCITE FUNCTIONAL ELECTRICAL STIMULATION SYSTEM**
Medical Device Name

Kelas **CLASS B** Jenama **XCITE CLINICAL STATION**
Class *Brand*

Kelompok **SYSTEM**
Group

Nama dan alamat pembuat: **RESTORATIVE THERAPIES INC 1434 FLEET ST BALTIMORE, MD 21231, USA., 21231 UNITED STATES**
Name and address of manufacturer

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Xcite Clinical Station	FA216218	Xcite Clinical Station is an advanced therapy system that utilizes functional electrical stimulation (FES) to provide active therapy in which coordinated electrical stimulation of peripheral nerves causes muscles to contract
2	XciteV2 Stimulator	SA220070	the stimulator (2nd generation)
3	XciteV2 Cart	SA220063	a cart to place the XciteV2 stimulator on (2nd generation)
4	XciteV2 Smart Battery	PP219918	the battery (user replaceable), meant to be connected inside the XciteV2 Stimulator
5	Stimulation Cable	PP217417	2 cables to connect between the XciteV2 stimulator and the electrodes
6	Power Adaptor	PP216206	power and charge the XciteV2 system
7	Electrode, 1.25" round	PP107289	The Electrode stick to the skin, connects to the Stimualtion Cable and deliver the stimulation
8	Electrode, sensitive, 1.5" x 3.5"	PP102738	The Electrode stick to the skin, connects to the Stimualtion Cable and deliver the stimulation

LAMPIRAN 1
Attachment 1

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
9	Electrode, sensitive, 2"x2"	PP100421	The Electrode stick to the skin, connects to the Stimualtion Cable and deliver the stimulation
10	Electrode 3"x5"	PP100420	The Electrode stick to the skin, connects to the Stimualtion Cable and deliver the stimulation
11	Electrode 3"x4"	PP100419	The Electrode stick to the skin, connects to the Stimualtion Cable and deliver the stimulation
12	Electrode 2"x2"	PP100418	The Electrode stick to the skin, connects to the Stimualtion Cable and deliver the stimulation
13	Electrode 2"x3.5"	PP100015	The Electrode stick to the skin, connects to the Stimualtion Cable and deliver the stimulation
14	Electrode, sensitive, 2"x4"	PP220276	The Electrode stick to the skin, connects to the Stimualtion Cable and deliver the stimulation
"End Of Product List"			

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 menjalankan pemeriksaan ke atas establismen pada bila-bila masa tanpa dimaklumkan terlebih dahulu.
The Authority reserves the right to conduct 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 Sijil ini tidak mengecualikan mana-mana keperluan perundangan lain yang terpakai untuk sesuatu peranti perubatan (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.)
This certificate does not exempt any other regulatory requirements applicable to the 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) .

1.11 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.

1.12 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 certificate 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.

3.3 Sijil Pendaftaran Peranti Perubatan boleh dibatalkan jika Wakil Diberi Kuasa ditamatkan lantikan oleh pembuat.
Medical Device Registration Certificate may be cancelled if Authorized Representative appoinment is terminated by the manufacturer.

4.0 HAK PIHAK BERKUASA
THE AUTHORITY OWNERSHIP

4.1 Sijil Pendaftaran Peranti Perubatan yang dikeluarkan fizikal atau maya 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 Condition