No. Siri: 065369
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: **GC657641159418**
Registration No.:

Tarikh Sah Pendaftaran: **26/09/2023 - 25/09/2028**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **MALAYSIAN DIAGNOSTICS CORPORATION SDN BHD**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

NO 1, JALAN SERINDIT 2 BANDAR PUCHONG JAYA,
47100
PUCHONG 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.

MURALITHARAN PARAMASUA
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GC657641159418**
Registration No.:

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

Nama Peranti Perubatan **PERRY SIGMA SERIES HYPERBARIC CHAMBERS**
Medical Device Name

Kelas **CLASS C** Jenama **PERRY**
Class *Brand*

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **PERRY BAROMEDICAL CORPORATION 3750 PROSPECT AVENUE RIVIERA BEACH FLORIDA, 33404 UNITED STATES**
Name and address of manufacturer

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	SIGMA 34 Monoplace Hyperbaric System	SIGMA 34	33.5 Inch internal diameter, 90 inch internal length, full-length clear acrylic, pneumatically controlled monoplace hyperbaric chamber
2	SIGMA 36 Monoplace Hyperbaric System	SIGMA 36	36 Inch internal diameter, 93 inch internal length, full-length clear acrylic, pneumatically controlled monoplace hyperbaric chamber
3	SIGMA 40 Monoplace Hyperbaric System	SIGMA 40	40.5 Inch internal diameter, 93 inch internal length, full-length clear acrylic, pneumatically controlled monoplace hyperbaric chamber
4	SIGMA 34 ELITE Monoplace Hyperbaric System	SIGMA 34 ELITE	33.5 Inch internal diameter, 90 inch internal length, full-length clear acrylic, computer & pneumatically controlled monoplace hyperbaric chamber
5	SIGMA 36 ELITE Monoplace Hyperbaric System	SIGMA 36 ELITE	36 Inch internal diameter, 93 inch internal length, full-length clear acrylic, computer & pneumatically controlled monoplace hyperbaric chamber

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
6	SIGMA 40 ELITE Monoplace Hyperbaric System	SIGMA 40 ELITE	40.5 Inch internal diameter, 93 inch internal length, full-length clear acrylic, computer & pneumatically controlled monoplace hyperbaric chamber
7	SIGMA 40-II Dualplace Hyperbaric System	SIGMA 40-II	40.5 Inch internal diameter, 93 inch internal length, full-length clear acrylic, pneumatically controlled multiplace hyperbaric chamber with 2-person gurney, integrated water-based fire-suppression system & Built-in Breathing System (BIBS) for patients
"End Of Product List"			

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

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) .