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: **GB139321360019**
Registration No.:

Tarikh Sah Pendaftaran: **27/11/2024 - 26/11/2029**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **DIPTECH INDUSTRIES SDN BHD**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

NO. 11, JALAN ANGSANA 1/3, TAMAN PERINDUSTRIAN ANGSANA,
08000 SUNGAI PETANI
KEDAH DARUL AMAN

Peranan establismen
Role of establishment

Pembuat
Manufacturer

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: **GB139321360019**
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Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan **DISPOSABLE BREATHING BAG (LATEX FREE)**
Medical Device Name

Kelas **CLASS B**
Class

Jenama **DIPTECH**
Brand

Kelompok **FAMILY**
Group

Nama dan alamat pembuat:
Name and address of manufacturer

DIPTECH INDUSTRIES SDN. BHD.
11, JALAN ANGSANA 1/3, TAMAN PERINDUSTRIAN ANGSANA SUNGAI PETANI, KEDAH.,
08000
MALAYSIA

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Disposable Breathing Bag (Latex Free) 0.5L	BB-0.5L-GDLF-DT	To be used as a system in respiratory care program and act as the reservoir for oxygen or air and help in inhalation in meeting the peak inspiratory flow (PIF) requirements.
2	Disposable Breathing Bag (Latex Free) 1L	BB-1L-GDLF-DT	To be used as a system in respiratory care program and act as the reservoir for oxygen or air and help in inhalation in meeting the peak inspiratory flow (PIF) requirements.
3	Disposable Breathing Bag (Latex Free) 1.5L	BB-1.5L-GDLF-DT	To be used as a system in respiratory care program and act as the reservoir for oxygen or air and help in inhalation in meeting the peak inspiratory flow (PIF) requirements.
4	Disposable Breathing Bag (Latex Free) 2L	BB-2L-GDLF-DT	To be used as a system in respiratory care program and act as the reservoir for oxygen or air and help in inhalation in meeting the peak inspiratory flow (PIF) requirements.

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
5	Disposable Breathing Bag (Latex Free) 3L	BB-3L-GDLF-DT	To be used as a system in respiratory care program and act as the reservoir for oxygen or air and help in inhalation in meeting the peak inspiratory flow (PIF) requirements.
6	Disposable Breathing Bag (Latex Free) 4L	BB-4L-GDLF-DT	To be used as a system in respiratory care program and act as the reservoir for oxygen or air and help in inhalation in meeting the peak inspiratory flow (PIF) requirements.
7	Disposable Breathing Bag (Latex Free) 5L	BB-5L-GDLF-DT	To be used as a system in respiratory care program and act as the reservoir for oxygen or air and help in inhalation in meeting the peak inspiratory flow (PIF) requirements.
"End Of Product List"			

Medical Device AUTHORITY MALAYSIA