

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: **GB99415938618**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

07/11/2023 - 06/11/2028

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

yang beralamat di:
which is located at:

**NO. 6, JALAN 15/22, TAMAN PERINDUSTRIAN
TIONG NAM, SEKSYEN 15,
40200 SHAH ALAM
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



No. Pendaftaran: **GB99415938618**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

07/11/2023 - 06/11/2028

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

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

Nama Peranti Perubatan **DRAEGER PHOTOTHERAPY LIGHT**
Medical Device Name

Kelas **CLASS B** Jenama **DRAEGER**
Class Brand

Kelompok **SYSTEM**
Group

Nama dan alamat pembuat: **DRAEGER MEDICAL SYSTEM, INC**
Name and address of manufacturer **3135 QUARRY ROAD TELFORD, PA, 18969 USA, 18969 UNITED STATES**

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	BiliLux LED phototherapy system	MU20100	The device BiliLux is a configurable LED phototherapy light. The BiliLux is designed to reduce serum bilirubin concentration in premature babies and neonates with hyperbilirubinemia by means of phototherapeutic radiation. It is intended for use with patients up to 3 months of age who weigh less than 10 kg (22 lb). The blue light of the phototherapy light lies within the wavelength range of 460 nm to 490 nm.
2	Phototherapy mask Eyemax 2, disposable, micro, 20	MP03770	Accessories
3	Phototherapy mask Eyemax 2, disposable, preemie, 20	MP03771	Accessories
4	Phototherapy mask Eyemax 2, disposable, regular, 20	MP03772	Accessories
5	BiliLux radiometer	MU26079	Accessories
6	USB flash drive	8416347	Accessories
7	BiliLux trolley	MU26076	Accessories



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
8	Cable holder for trolley pole	G13171	Accessories
9	BiliLux spring arm	MU26077	Accessories
10	Rail clamp for phototherapy light	MP00615	Accessories
11	Compact rail	2M85337	Accessories
12	Clamp	2M85274	Accessories
13	Kit, GCX pivot rail	4118453	Accessories
"End Of Product List"			

