

Tende CareBlue

LED Phototherapy Device for Neonates

Tende CareBlue intensive LED phototherapy unit for treatment of neonates with high bilirubin levels.



First phototherapy unit with Color TFT Touch Screen Monitor

High-density light power with fan-free LED technology

5 levels of light intensity

Red focus light (for optimal coverage of the treatment area)

White examination light

User-friendly interface

Foldable screen

Audible and visual alarm

2 working modes (standard and timer mode)

Easy to use pneumatic height adjustment

Angle adjustment (360°)

Low power consumption

> 70.000h LED lifetime

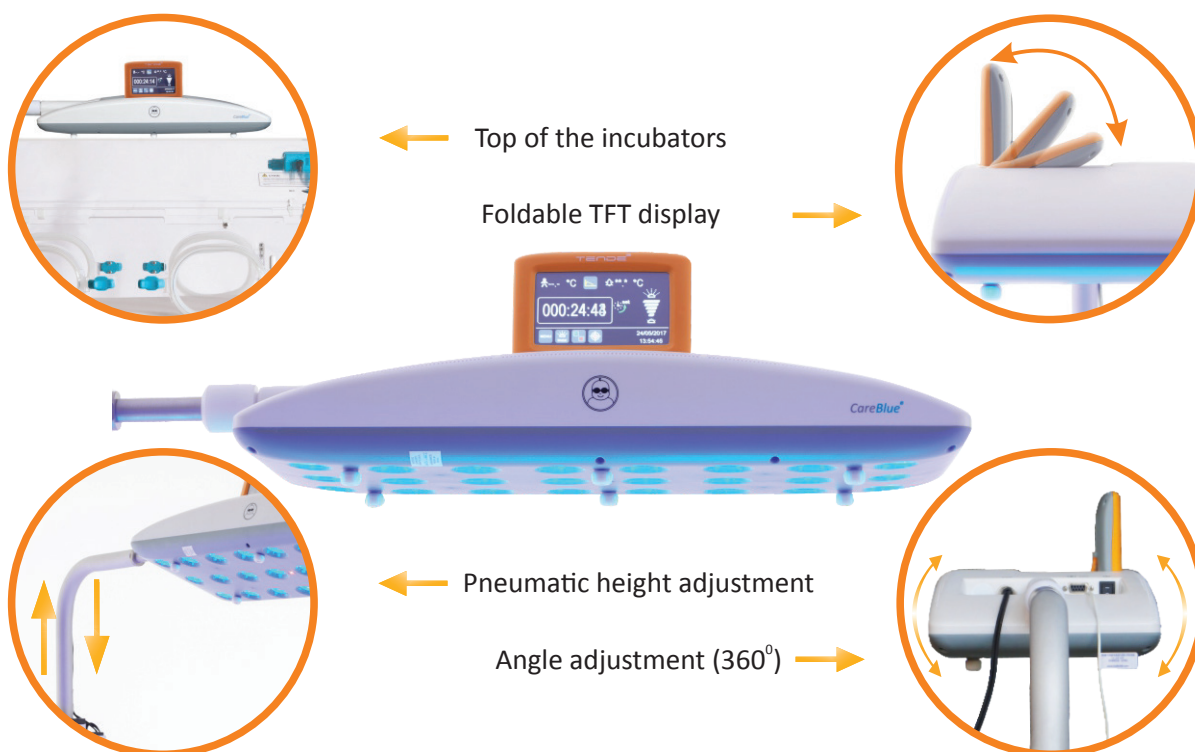
Counter of LED lifetime

Silent, lightweight, durable stand unit

Compatible with baby incubators, infant warmers, and bassinets

7 language options

Upgradable language menu



FEATURES

LIGHT SOURCE

Light Source	Blue LED (24 pcs, Super Bright LED)
Wavelength	460nm (± 2%)
Light Intensity (Standard)	Max. 60 $\mu\text{W}/\text{cm}^2/\text{nm}$ (±10%) Min. 15 $\mu\text{W}/\text{cm}^2/\text{nm}$ (±10%) (From 40 cm)
Intensive Light Intensity (Optional)	Max. 120 $\mu\text{W}/\text{cm}^2/\text{nm}$ (±10%) Min. 30 $\mu\text{W}/\text{cm}^2/\text{nm}$ (±10%) (From 40 cm)
Effective Area	45 cm x 20 cm (From 40 cm)
LED Life Time	> 70,000 Hours (Check the user manual for technical details)

ELECTRICAL SPECIFICATIONS

Operating Voltage	~80 - 264 VAC 50 /60 Hz (MDD Class/Safety)
Power Consumption	80 VA, Max 45 W

ENVIRONMENTAL REQUIREMENTS

Operating Temperature	15°C to 40°C
Operating R.Humidity	< 90%
Storage Temperature	~ -20°C to +50°C
Storage R. Humidity	< 90%

GENERAL

LCD Graphic Display	4.3 inches Color TFT Touch Screen
Dimensions L W H (Therapy Module)	~ 52.2 cm x 20.6 cm x 9.3 cm
Wheels	2/3 With Breaks
Height Adjustment	110 cm - 154 cm (± 2%)
Tilt Adjustment (with stand unit)	Yes
Wheel Height	~ 6.3 cm
Weight	~ 2.5 Kg (9.2 Kg With Stand Unit) (± 1%)
Noise Level	Zero dBA

APPLICATION

Treatment Time Adjustment	Yes (Hours and Minutes hhh:mm)
Visual Alarms	Yes
Audible Alarms	Yes
Light Intensity	5 Levels
Date & Time Display	Yes
LED Life Counter	Yes (Individual Level and Total LED Counters)
Baby Skin Temperature	Yes (Optional)
White LED examination lamp	Yes (Optional)

MEDICAL DEVICES DIRECTIVES (MDD)

Manufacturer MDD Conformity	Class IIb - Production Quality Assurance
Equipment Conformity	EN60601-1, EN60601-1-2, EN60601-2-50

Exclusive Distributor (Malaysia)



MEDIK GEN SDN BHD
(Wholly-Owned Subsidiary of LKL INTERNATIONAL BERHAD)

201401038690 (1114838-W)

Wisma LKL, No. 3, Jalan BS 7/18,
Kawasan Perindustrian Bukit Serdang,
43300 Seri Kembangan,
Selangor Darul Ehsan, Malaysia.

For Further Enquiries
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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: **GB7690726-235398**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

30/06/2026 - 29/06/2031

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

yang beralamat di:
which is located at:

**NO 15, JALAN BS7/20, TAMAN PERINDUSTRIAN
BUKIT SERDANG, ,
43300 SERI KEMBANGAN
SELANGOR DARUL EHSAN**

Peranan establismen
Role of establishment

Wakil Diberi Kuasa
Authorized Representative

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: **GB7690726-235398**
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29/06/2031

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

Nama Peranti Perubatan **TENDE CAREBLUE LED PHOTOTHERAPY DEVICE**
Medical Device Name

Kelas **CLASS B**
Class

Jenama **TENDE**
Brand

Kelompok **SYSTEM**
Group

Nama dan alamat pembuat:
Name and address of manufacturer

**TENDE ELEKTRONIK YAZILIM MÜHENDISLIK İLETİSİM MAKİNA SANAYİ VE
TİCARET LİMİTED SİRKETİ
AHI EVRAN OSB MAHALLESİ AKHUN CAD. NO: 5/1 SINCAN/ANKARA,
06935
TURKEY**

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Tende CareBlue LPT-240-2 LED Phototherapy Device	M02.00001.00.00	Tende CareBlue LED Phototherapy Device is designed for treatment of neonatal hyperbilirubinemia.
2	Tende CareBlue-N LED Phototherapy Device	M02.00002.00.00	Tende CareBlue LED Phototherapy Device is designed for treatment of neonatal hyperbilirubinemia.
3	Skin Temperature Measurement Feature Including Reusable Skin Probe	O02.00001.00.00	Skin Temperature Measurement Feature Including Reusable Skin Probe
4	White LED Examination Lamp Feature	O02.00002.00.00	White LED Examination Lamp Feature
5	CareBlue Screen Top Cover	Y02.00020.**.**	Screen Top Cover
6	CareBlue Transparent Screen Protective	H02.00280.**.**	Transparent Screen Protective
7	CareBlue TFT Touch Screen	H01.00338.00.00	TFT Touch Screen
8	CareBlue INT Board	Y01.00220.**.**	INT Board
9	CareBlue Transparent Cover Between CPU and INT Boards	H02.00279.**.**	Transparent Cover Between CPU and INT Boards
10	CareBlue CPU Board	Y01.00173.**.**	CPU Board
11	CareBlue Clock Battery	H01.00776.00.00	Clock Battery



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
12	CareBlue Screen Bottom Cover	Y02.00019.**.**	Screen Bottom Cover
13	CareBlue Screen Support	Y02.00021.**.**	Screen Support
14	CareBlue Light Source Unit Top Cover	Y02.00018.**.**	Light Source Unit Top Cover
15	CareBlue DRV Board	Y01.00174.**.**	DRV Board
16	CareBlue WLED Kartı	Y01.00176.**.**	WLED Kartı
17	CareBlue LED Array with cable	Y01.00438.**.**	LED Array with cable
18	CareBlue Lens	H02.00395.00.00	Lens
19	CareBlue Light Source Unit Bottom Cover	Y02.00017.**.**	Light Source Unit Bottom Cover
20	CareBlue TARGET Board	Y01.00175.**.**	TARGET Board
21	CareBlue Light Source Unit Suction Cup or Silicone Pod	Y02.00853.**.**	Light Source Unit Suction Cup or Silicone Pod
22	CareBlue Plastic Suppot Pipe Part	Y02.00070.**.**	Plastic Suppot Pipe Part
23	CareBlue Stand Unit	Y02.00796.**.**	Stand Unit
24	CareBlue T Unit of Stand (without casters)	Y02.00376.**.**	T Unit of Stand (without casters)
25	CareBlue Assembled Height Adjustment Unit	Y02.00729.**.**	Assembled Height Adjustment Unit
26	CareBlue Light Source Unit Angle Adjustment Mechanism	Y02.00789.**.**	Light Source Unit Angle Adjustment Mechanism
27	CareBlue Height Adjustment Knobe	Y02.00742.**.**	Height Adjustment Knobe
28	CareBlue Caster with Brake	H02.00782.00.00	Caster with Brake
29	CareBlue Caster without Brake	H02.00781.00.00	Caster without Brake
30	CareBlue Flat Cable Between CPU Board and Screen	H01.00224.00.00	Flat Cable Between CPU Board and Screen
31	CareBlue LED Array With Cable	Y01.00420.**.**	LED Array With Cable
32	CareBlue ACCONONOFF Cable	Y01.00441.**.**	ACCONONOFF Cable
33	CareBlue ONOFFPS Cable	Y01.00442.**.**	ONOFFPS Cable
34	CareBlue PSDRV Cable	Y01.00443.**.**	PSDRV Cable
35	CareBlue RS232DRV Cable	Y01.00036.**.**	RS232DRV Cable
36	CareBlue SKINDRV Cable	Y01.00037.**.**	SKINDRV Cable
37	CareBlue TARGET Cable	Y01.00038.**.**	TARGET Cable



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
38	CareBlue DRVCPU Cable	Y01.00033.**.**	DRVCPU Cable
39	CareBlue WLED Cable	Y01.00039.**.**	WLED Cable
40	CareBlue ONOFF Switch	H01.00800.00.00	ONOFF Switch
41	CareBlue Power Cord	H01.00232.00.00	Power Cord
42	CareBlue Reusable Skin Temperature Probe	Y05.00006.**.**	Reusable Skin Temperature Probe
43	Phototherapy Eye Protection Mask, Small	H02.00705.00.00	Phototherapy Eye Protection Mask, Small
44	Phototherapy Eye Protection Mask, Medium	H02.00704.00.00	Phototherapy Eye Protection Mask, Medium
45	Phototherapy Eye Protection Mask, Large	H02.00703.00.00	Phototherapy Eye Protection Mask, Large
46	CareBlue Power Supply	H01.01920.00.00	Power Supply
"End Of Product List"			

