No. Siri: 021549

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:

GMD51062747518A

Tarikh Sah Laku Pendaftaran: Registration Validity Date:

20/09

26/09/2018 - 25/09/2023

Registration No.:

Sijil ini adalah dengan ini dikeluarkan kepada: This Certificate is hereby issued to:

**JEEV WIN TRADING** 

yang beralamat di:

NO. 15 & 16, TAMAN SLIM INDAH 2,

of:

SLIM RIVER 35800 PERAK

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:

GMD51062747518A

Registration No.:

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

Nama Peranti Perubatan Medical Device Name

PD DRESSING SET

Kelas Class

CLASS A

Brand Brand

HARSH MED

Kelompok

Group

Kegunaan Yang Diniatkan

SET

Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.

Intended Use NO. 15 & 16, TAMAN SLIM INDAH 2,

Nama dan alamat pembuat: Name and address of manufacturer

**SLIM RIVER** 35800 PERAK

APPENDIX			
No.	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1.	Cotton Balls 0.5 g - 10 pieces	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
2.	3 Compartment Tray - 1 piece	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
3.	Sterile Field 45 x 45 cm - 1 piece,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
4.	Key Hole Drape - 2 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
5.	Hand Towel - 2 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
6.	Gallipot 60 ml - 2 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
7.	Forcep 12.5 cm - 2 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
8.	Gauze Swab 5 x 5 cm x 8 ply - 5 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
9.	Cotton Balls 0.5 g - 10 pieces	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the * skin such as catheters, and as a secondary dressing.
10.	Gauze Swab 7.5 x 7.5 cm x 8 ply - 15 piece	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
11.	3 Compartment Tray - 1 piece	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
12.	Sterile Field 45 x 45 cm - 1 piece,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
13.	Key Hole Drape - 2 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
14.	Hand Towel - 2 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
15.	Gallipot 60 ml - 2 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
16.	Forcep 12.5 cm - 2 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
17.	Gauze Swab 5 x 5 cm x 8 ply - 5 pieces,	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.
18.	Gauze Swab 7.5 x 7.5 cm x 8 ply - 15 piece	PDS-PDS-TY1-SET	Intended for woundcare applications, securing objects to the skin such as catheters, and as a secondary dressing.