

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: **GD3500020-41882**  
Registration No.:

Tarikh Sah Pendaftaran: **13/03/2020 - 12/03/2025**  
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **BEN WAY ENTERPRISES SDN BHD**  
*This certificate is hereby issued to:*

yang beralamat di:  
*which is located at:*

**NO: 8, JALAN RAMIN 3, BANDAR BOTANIC,  
KLANG ,  
41200  
KLANG 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.*



**AHMAD SHARIFF BIN HAMBALI**  
KETUA EKSEKUTIF  
CHIEF EXECUTIVE  
PIHAK BERKUASA PERANTI PERUBATAN  
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Butir-butir peranti perubatan yang didaftarkan  
Particulars of the registered medical device

Nama Peranti Perubatan **INSORB SUBCUTICULAR SKIN STAPLER**  
Medical Device Name

Kelas **CLASS D** Jenama **INSORB**  
Class Brand

Kelompok **FAMILY**  
Group

Nama dan alamat pembuat: **INCISIVE SURGICAL, INC**  
Name and address of manufacturer **14405-21ST AVENUE NORTH, SUITE 130, PLYMOUTH, MINNESOTA, 55447 UNITED STATES**

**APPENDIX**

<b>NO</b>	<b>NAME AS PER DEVICE LABEL</b>	<b>IDENTIFIER</b>	<b>BRIEF DESCRIPTION OF ITEM</b>
1	INSORB STAPLER	2010	10 PRE-LOADED STAPLES
2	INSORB STAPLER	2015	15 PRE-LOADED STAPLES
3	INSORB STAPLER	2020	20 PRE-LOADED STAPLES
4	INSORB STAPLER	2025	25 PRE-LOADED STAPLES
5	INSORB STAPLER	2030	30 PRE-LOADED STAPLES
"End Of Product List"			