

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: **GB3310421-62140**
Registration No.:

Tarikh Sah Pendaftaran:
Registration Validity Date:

18/05/2026 - 17/05/2031

Sijil ini adalah dengan ini diberi kepada:
This certificate is hereby issued to:

ROCKY SCIENTIFIC INSTRUMENTATION

yang beralamat di:
which is located at:

**UNIT 10-2F JALAN SETIA PERDANA BB U13/BB ,
SETIA ALAM,
40170 SHAH ALAM
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.



A handwritten signature in black ink, appearing to read 'Muralitharan Paramasua'.

MURALITHARAN PARAMASUA
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 **HIGH PRESSURE ANGIOGRAPHIC SYRINGE AND ACCESSORIES FOR**
Medical Device Name **SINGLE USE**

Kelas **CLASS B** Jenama **YESO-MED**
Class Brand

Kelompok **FAMILY OF SYSTEM**
Group

Nama dan alamat pembuat: **WUXI YUSHOU MEDICAL APPLIANCES CO., LTD**
Name and address of manufacturer **NO. 115, NONGXINHE ROAD XISHAN DISTRICT, WUXI CITY, JIANGSU PROVINCE , PEOPLE'S REPUBLIC OF CHINA, 214191 CHINA**

APPENDIX

Nama Sistem **HIGH PRESSURE ANGIOGRAPHIC SYRINGE AND ACCESSORIES FOR SINGLE USE**
System Name

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	High Pressure Angiographic Syringe and Accessories for Single Use NE Series 200ml Syringe	300200B	For Nemoto CT use
2	High Pressure Angiographic Syringe and Accessories for Single Use MEDT Series A 200ml Syringe	400200A	For Medtron CT injector use
3	High Pressure Angiographic Syringe and Accessories for Single Use MEDR Series B 200ml Syringe	400200B	For Medtron CT injector use
4	High Pressure Angiographic Syringe and Accessories for Single Use LF Series 200ml Syringe	200200A	For LF CT injector use
5	High Pressure Angiographic Syringe and Accessories for Single Use MEDR Series 150ml Syringe	100150A	For Medrad angio injector use
6	High Pressure Angiographic Syringe and Accessories for Single Use LF Series A 150ml Syringe	200150A	For LF angio injector use



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
7	High Pressure Angiographic Syringe and Accessories for Single Use LF Series B 150ml Syringe	200150B	For LF angio injector use
8	150cm CT Tube	150-CT Ctube	150cm CT Tube
9	15cm Y tube with 2 check valves	Y15-2CV	15cm Y tube with 2 check valves
10	150cm Y tube with 2 check valves	Y150-2CV	150cm Y tube with 2 check valves
11	J Quick Fill Tube	J-FillTube	J Quick Fill Tube
12	Multi Use Tubing	12HRS-MUT	Multi Use Tubing
13	High Pressure Angiographic Syringe and Accessories for Single Use NEMOTO Series 130ml Syringe	300130A	For Nemoto Angiography injector used
14	150cm Straight tube	150-CT Stube	150cm Straight tube
15	15cm Straight tube	15-CT Stube	15cm Straight tube
16	High Pressure Angiographic Syringe and Accessories for Single Use LF MRI Series 60ml Syringe	10060C/10060C	For LF MRI injector use
17	High Pressure Angiographic Syringe and Accessories for Single Use	100100C/10060A	Medrad Spectris Solaris EP (65mL / 115mL + tubing)
18	High Pressure Angiographic Syringe and Accessories for Single Use	100060A/100060A	Nemoto sonic shot (100060A/100060A)
19	High Pressure Angiographic Syringe and Accessories for Single Use	40060A/40060A	Medtron accutron MR (65mL / 200mL + tubing)
20	High Pressure Angiographic Syringe and Accessories for Single Use	100200B	Medrad 200ml single pack with fill tube (suitable for Medrad Stellant)
"End Of Product List"			