

No. Siri: **003024**

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: **GC16934169017**
Registration No.:

Tarikh Sah Laku Pendaftaran:
Registration Validity Date:

27/02/2017 - 26/02/2022

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

URO TECHNOLOGY SDN. BHD.

yang beralamat di:
of:

**LOT 2491, BATU 39 1/2, PONTIAN BESAR
PONTIAN
82000 JOHOR**

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 be 'ZAMANE BIN ABDUL RAHMAN', written over a horizontal line.

ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
Pihak Berkuasa Peranti Perubatan
Medical Device Authority

LAMPIRAN 1
Attachment 1



No. Pendaftaran: GC16934169017
Registration No.:

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

Nama Peranti Perubatan: STERILE URETHRAL CATHETERS
Medical Device Name

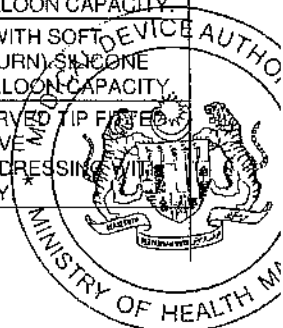
Kelas: CLASS C Brand: CHROMA
Class Brand

Kelompok: FAMILY
Group

Nama dan alamat pembuat: URO TECHNOLOGY SDN. BHD.
Name and address of manufacturer: LOT 2491, BATU 39 1/2, PONTIAN BESAR,
82000 PONTIAN, JOHOR, MALAYSIA

APPENDIX

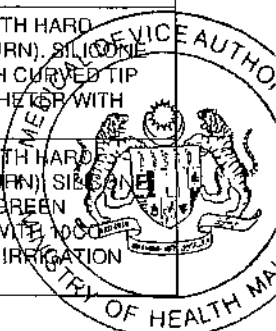
No.	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1.	SILICONISED 2 WAY STANDARD MALE(HARD VALVE)10CC BALLOON	2111210- 2113010	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE(NONRETURN). SILICONE DRESSING WITH 10CC BALLOON CAPACITY.
2.	SILICONISED 2 WAY STANDARD MALE(HARD VALVE)30CC BALLOON	2111230- 2113030	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE(NONRETURN). SILICONE DRESSING WITH 30CC BALLOON CAPACITY.
3.	SILICONISED 2 WAY STANDARD MALE (SOFT VALVE)10CC BALLOON	2121210- 2123010	LENGTH : 40CM .FITTED WITH SOFT RUBBER VALVE(NONRETURN). SILICONE DRESSING WITH 10CC BALLOON CAPACITY.
4.	SILICONISED 2 WAY STANDARD MALE (SOFT VALVE)30CC BALLOON	2121230- 2123030	LENGTH : 40CM .FITTED WITH SOFT RUBBER VALVE(NONRETURN). SILICONE DRESSING WITH 30CC BALLOON CAPACITY.
5.	SILICONISED 2 WAY STANDARD FEMALE (HARD VALVE)10CC BALLOON	4111210-4112610	LENGTH : 22CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) . SILICONE DRESSING WITH 10CC BALLOON CAPACITY.
6.	SILICONISED 2 WAY STANDARD FEMALE (HARD VALVE)30CC BALLOON	4111230-4112630	LENGTH : 22CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) . SILICONE DRESSING WITH 30CC BALLOON CAPACITY.
7.	SILICONISED 2 WAY PAEDIATRIC (HARD VALVE)3CC BALLOON	5110803	LENGTH : 30CM .FITTED WITH HARD PLASTIC VALVE(NONRETURN).SILICONE DRESSING WITH 3CC BALLOON CAPACITY.
8.	SILICONISED 2 WAY PAEDIATRIC (HARD VALVE)5CC BALLOON	5110805-5111005	LENGTH : 30CM .FITTED WITH HARD PLASTIC VALVE(NONRETURN).SILICONE DRESSING WITH 5CC BALLOON CAPACITY.
9.	SILICONISED 2 WAY PAEDIATRIC (SOFT VALVE)3CC BALLOON	5120603	LENGTH : 30CM .FITTED WITH SOFT RUBBER VALVE (NONRETURN). SILICONE DRESSING WITH 3CC BALLOON CAPACITY.
10.	SILICONISED 2 WAY PAEDIATRIC (SOFT RUBBER VALVE)5CC BALLOON	5120805-5121005	LENGTH : 30CM .FITTED WITH SOFT RUBBER VALVE(NONRETURN).SILICONE DRESSING WITH 5CC BALLOON CAPACITY.
11.	SILICONISED 2 WAY STANDARD MALE TIEMANN(HARD VALVE)10CC BALLOON	6111210-6112610	LENGTH : 40CM WITH CURVED TIP FITTED WITH HARD PLASTIC VALVE (NONRETURN).SILICONE DRESSING WITH 10CC BALLOON CAPACITY.
12.		6111230-6112630	



	SILICONISED 2 WAY STANDARD MALE TIEMANN(HARD VALVE)30CC BALLOON		LENGTH : 40CM WITH CURVED TIP FITTED WITH HARD PLASTIC VALVE (NONRETURN).SILICONE DRESSING WITH 30CC BALLOON CAPACITY.
13.	SILICONISED 3 WAY STANDARD MALE (HARD VALVE)10CC BALLOON	3111610-3112610	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) SILICONE DRESSING WITH 10CC BALLOON CAPACITY WITH IRRIGATION LUMEN.
14.	SILICONISED 3 WAY STANDARD MALE (HARD VALVE)30CC BALLOON	3111630-3112630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) SILICONE DRESSING WITH 30CC BALLOON CAPACITY WITH IRRIGATION LUMEN.
15.	SILICONISED 3 WAY STANDARD MALE (SOFT VALVE)10CC BALLOON	3121610-3122610	LENGTH : 40CM .FITTED WITH SOFT RUBBER VALVE(NONRETURN). SILICONE DRESSING WITH 10CC BALLOON CAPACITY WITH IRRIGATION LUMEN.
16.	SILICONISED 3 WAY STANDARD MALE (SOFT VALVE)30CC BALLOON	3121630-3122630	LENGTH : 40CM .FITTED WITH SOFT RUBBER VALVE(NONRETURN). SILICONE DRESSING WITH 30CC BALLOON CAPACITY WITH IRRIGATION LUMEN.
17.	SILICONISED 2 WAY HAEMATURIA NELATON (HARD VALVE)30CC BALLOON	2211830-2212630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 30CC BALLOON CAPACITY WITH REINFORCED NYLON.
18.	SILICONISED 2 WAY HAEMATURIA COUVELAIRE (HARD VALVE)30CC BALLOON	2311830-2312630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 30CC BALLOON CAPACITY WITH REINFORCED NYLON AND FLUTE TIP.
19.	SILICONISED 2 WAY HAEMATURIA DUFOR (HARD VALVE)60CC BALLOON	2411860-2412660	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 60CC BALLOON CAPACITY WITH REINFORCED NYLON AND OPENED ENDED CURVED TIP.
20.	SILICONISED 2 WAY HAEMATURIA MERCIER (HARD VALVE)60CC BALLOON	2511860-2512660	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 60CC BALLOON CAPACITY WITH REINFORCED NYLON AND CURVED TIP.
21.	SILICONISED 2 WAY HAEMATURIA FROHMULLER (HARD VALVE)60CC BALLOON	2611860-2612660	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 60CC BALLOON CAPACITY WITH REINFORCED NYLON AND STAGGERED EYES WITH CURVED TIP.
22.	SILICONISED 3 WAY HAEMATURIA NELATON (HARD VALVE)30CC BALLOON	3211830-3212630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 30CC BALLOON CAPACITY WITH REINFORCED NYLON AND IRRIGATION LUMEN.
23.	SILICONISED 3 WAY HAEMATURIA COUVELAIRE (HARD VALVE)30CC BALLOON	3311830-3312630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 30CC BALLOON CAPACITY WITH REINFORCED NYLON AND FLUTE TIP WITH IRRIGATION LUMEN.
24.	SILICONISED 3 WAY HAEMATURIA DUFOR (HARD VALVE)60CC BALLOON	3411860-3412660	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 60CC BALLOON CAPACITY WITH REINFORCED NYLON AND OPENED ENDED CURVED TIP WITH IRRIGATION LUMEN.
25.	SILICONISED 3 WAY HAEMATURIA MERCIER (HARD VALVE)60CC BALLOON	3511860-3512660	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 60CC BALLOON CAPACITY WITH REINFORCED NYLON AND CURVED TIP WITH IRRIGATION LUMEN.
26.	SILICONISED 3 WAY HAEMATURIA FROHMULLER (HARD VALVE)60CC BALLOON	3611860-3612660	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NON RETURN). SILICONE DRESSING WITH 60CC BALLOON CAPACITY WITH REINFORCED NYLON AND



			STAGGERED EYES WITH CURVED TIP AND IRRIGATION LUMEN.
27.	2 WAY GREEN SILICONE ELASTOMER COATED CATHETER (HARD VALVE)10CC BALLOON	2131210-2132810	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) SILICONE ELASTOMER COATED ON GREEN PIGMENTED CATHETER WITH 10CC BALLOON CAPACITY .
28.	2 WAY GREEN SILICONE ELASTOMER COATED CATHETER (HARD VALVE)30CC BALLOON	2131230-2132830	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) SILICONE ELASTOMER COATED ON GREEN PIGMENTED CATHETER WITH 30CC BALLOON CAPACITY .
29.	2 WAY PAEDIATRIC GREEN SILICONE(HARD VALVE) 3CC BALLOON	5130603	LENGTH : 30CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED ON GREEN PIGMENTED CATHETER WITH 3CC BALLOON CAPACITY. .
30.	2 WAY PAEDIATRIC GREEN SILICONE(HARD VALVE) 5CC BALLOON	5130805-5131005	LENGTH : 30CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED ON GREEN PIGMENTED CATHETER WITH 5CC BALLOON CAPACITY. .
31.	2 WAY BLUE SILICONE ELASTOMER COATED CATHETER (HARD VALVE)10 CC BALLOON	2171210-2172810	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) SILICONE ELASTOMER COATED ON BLUE PIGMENTED CATHETER WITH 10CC BALLOON CAPACITY .
32.	2 WAY BLUE SILICONE ELASTOMER COATED CATHETER (HARD VALVE)30 CC BALLOON	2171230-2172830	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) SILICONE ELASTOMER COATED ON BLUE PIGMENTED CATHETER WITH 30CC BALLOON CAPACITY .
33.	2 WAY BLUE PAEDIATRIC SILICONE ELASTOMER COATED CATHETER(HARD VALVE)3 CC BALLOON	5170603	LENGTH : 30CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED ON BLUE PIGMENTED CATHETER WITH 3CC BALLOON CAPACITY.
34.	2 WAY BLUE PAEDIATRIC SILICONE ELASTOMER COATED CATHETER(HARD VALVE)5 CC BALLOON	5170805-5171005	LENGTH : 30CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED ON BLUE PIGMENTED CATHETER WITH 5CC BALLOON CAPACITY.
35.	2 WAY GREEN SILICONE ELASTOMER COATED TIEMANN CATHETER (HARD VALVE)10CC BALLOON	6131210-6132610	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED WITH CURVED TIP ON GREEN PIGMENTED CATHETER WITH 10CC BALLOON CAPACITY.
36.	2 WAY GREEN SILICONE ELASTOMER COATED TIEMANN CATHETER (HARD VALVE)30CC BALLOON	6131230-6132630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED WITH CURVED TIP ON GREEN PIGMENTED CATHETER WITH 30CC BALLOON CAPACITY.
37.	2 WAY BLUE SILICONE ELASTOMER COATED TIEMANN CATHETER (HARD VALVE)10CC BALLOON	6171210-6172610	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED WITH CURVED TIP ON BLUE PIGMENTED CATHETER WITH 10CC BALLOON CAPACITY.
38.	2 WAY BLUE SILICONE ELASTOMER COATED TIEMANN CATHETER (HARD VALVE)30CC BALLOON	6171230-6172630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED WITH CURVED TIP ON BLUE PIGMENTED CATHETER WITH 30CC BALLOON CAPACITY.
39.	3 WAY STANDARD GREEN SILICONE ELASTOMER COATED (HARD VALVE)10 CC BALLOON	3131610-3132610	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN) SILICONE ELASTOMER COATED ON GREEN PIGMENTED CATHETERS WITH 10CC BALLOON CAPACITY WITH IRRIGATION LUMEN.



40.	3 WAY STANDARD GREEN SILICONE ELASTOMER COATED (HARD VALVE)30 CC BALLOON	3131630-3132630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED ON GREEN PIGMENTED CATHETERS WITH 30CC BALLOON CAPACITY WITH IRRIGATION LUMEN.
41.	3 WAY STANDARD BLUE SILICONE ELASTOMER COATED (HARD VALVE)10CC BALLOON	3171610-3172610	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED ON BLUE PIGMENTED CATHETERS WITH 10CC BALLOON CAPACITY WITH IRRIGATION LUMEN.
42.	3 WAY STANDARD BLUE SILICONE ELASTOMER COATED (HARD VALVE)30CC BALLOON	3171630-3172630	LENGTH : 40CM .FITTED WITH HARD PLASTIC VALVE (NONRETURN). SILICONE ELASTOMER COATED ON BLUE PIGMENTED CATHETERS WITH 30CC BALLOON CAPACITY WITH IRRIGATION LUMEN. *
43.	1 WAY NELATON	1100800-1102800	LENGTH : 40 CM WITHOUT BALLOON

