

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: **GC7567445516**
Registration No.:

Tarikh Sah Laku Pendaftaran:
Registration Validity Date:

19/07/2016 - 18/07/2021

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.



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

LAMPIRAN 1
Attachment 1



No. Pendaftaran: **GC7567445516**
Registration No.:

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

Nama Peranti Perubatan **STERILE URETHRAL CATHETERS**
Medical Device Name

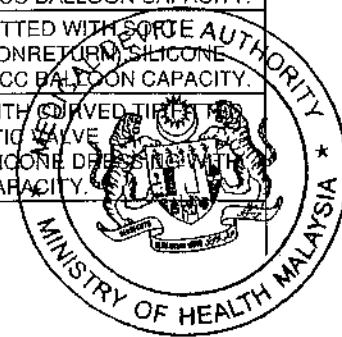
Kelas **CLASS C** Brand **UROCARE**
Class Brand

Kelompok **FAMILY**
Group

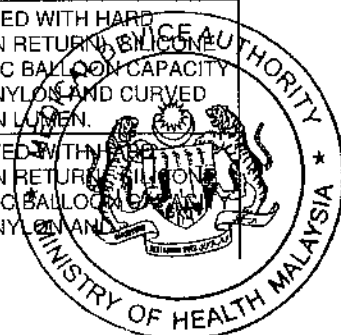
Nama dan alamat pembuat: **URO TECHNOLOGY SDN BHD**
Name and address of manufacturer **LOT 2491, BATU 39 1/2, PONTIAN BESAR,
82000 PONTIAN, JOHOR, MALAYSIA**

APPENDIX

| No. | NAME AS PER DEVICE LABEL | IDENTIFIER | BRIEF DESCRIPTION OF ITEM |
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| 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 | 5110603 | 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 WITH HARD PLASTIC VALVE (NONRETURN).SILICONE DRESSING WITH 10CC BALLOON CAPACITY. |
| 12. | | 6111230-6112630 | |



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| | 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 DUFOUR (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)80CC 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 DUFOUR (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 |



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| | | | 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 IRRIGATION LUMEN. |



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| 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 | 1100800-1102600 | LENGTH : 40 CM WITH OUT BALLOON |

