

# **THERAPEUTIC GOODS ACT 1989**

## **THERAPEUTIC GOODS ORDER No. 59**

### **Polymer Urethral Catheters for General Medical use**

I, John Cable, delegate of the Minister for Health and Family Services for the purposes of the exercise of the Minister's powers under Section 10 of the **Therapeutic Goods Act 1989**, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the said Act, HEREBY:

REVOKE, on and from the date this Order is gazetted, Therapeutic Goods Order No, 38, "Single-Use Urethral Catheters (Sterile) for General Medical Use" which commenced to operate on 16 May 1991; and

DETERMINE that the matters specified in clauses 1 to 10 inclusive and Appendix A and B in the document titled "**AS/NSZ 2696:1996 Australian/New Zealand Standard, Medical devices – Polymer urethral catheters for general medical use**", published by Standards Australia on 5 July 1996 ("the Standard") and as modified below, shall constitute standards for all polymer urethral catheters for general medical use.

### **MODIFICATIONS TO THE STANDARD**

(a) **CLAUSE 2 "REFERENCED DOCUMENTS"**

Add to the top of the list of referenced documents in Clause 2 the Australian Standard:

"1199 Sampling procedures and tables for inspection by attributes (AS 1199-1988)";

(b) **NEW CLAUSE 11**

Insert after Clause 10 the following new Clause:

"11 The table below sets out the acceptable quality levels to be applied to the tests described in the standard, as set out in "Table 1 - Sample size code letters" and "Table 2-A - Single sampling plans for normal inspection (Master table)" in AS 1199.";

AS/NZS 2696:1996 Clause No.	Inspection Level	Acceptable Quality Level
6.4.2	A minimum of 3 replicates shall be used for the test samples and controls used to test for cytotoxicity, refer to Appendix B	
6.4.4	As defined in TGO 11	As defined in TGO 11
7.2.1.	S-2	4.0
7.2.2	S-2	4.0
7.3	S-2	4.0
8.1.2	S-2	4.0
8.1.4	S-2	4.0
8.1.5	S-2	1.5



8.2.2	S-2	4.0
8.2.5	S-2	1.5
8.2.6	S-2	4.0
8.2.7	S-2	1.5
8.2.8	S-2	4.0
8.2.9	S-2	1.5
9.1	S-2	1.5
10.1	S-2	1.5
10.2	S-2	1.5
10.3	S-2	1.5

- (c) NEW CLAUSE 12  
Insert after Clause 11 the following new Clause:

“12 A reference in this Order to another document is taken to be a reference to the document as in force on the date this Order is gazetted.”.

This Order commences on the date this Order is gazetted.

Dated on this 7<sup>th</sup> day of April 1997.

John Cable  
Delegate of the Minister for Health and Family Services