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AS/NZS 2696:1996

Australian/New Zealand Standard®

Medical devices—Polymer urethral catheters for general medical use

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/1, Hypodermic and Other Equipment for General Medical Use. It was approved on behalf of the Council of Standards Australia on 4 April 1996 and on behalf of the Council of Standards New Zealand on 25 March 1996. It was published on 5 July 1996.

The following interests are represented on Committee HT/1:

Alfred Hospital, Vic.
Association of Certification Bodies
Auckland Environmental Protection Agency
Australian Chamber of Commerce and Industry
Australian Medical Association
Commercial Services Group, N.S.W.
Commonwealth Department of Human Services and Health
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Medical devices—Polymer urethral catheters for general medical use

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/1, Hypodermic and Other Equipment for General Medical Use, to supersede AS 2696—1989, *Medical equipment—Single-use urethral catheters (sterile) for general medical use*.

The objective of this Standard is to provide users with a catheter that is biocompatible, correctly labelled, and with acceptable flow rates and balloon performance. The Standard was revised in 1989 with the objective of resolving practical problems encountered in areas such as sampling, testing and balloon symmetry.

The Standard allows for the use of 'ml', 'cm^3' or 'cc' for expressing the rated balloon capacity, as all types of catheters with balloons are presently imported and 'cc' is well understood in the medical industry.

The committee was concerned with reports of severe allergic reactions to medical devices containing latex. Naturally occurring proteins in the latex itself appear to be the primary source of such a reaction. Although it is not now known how much protein is likely to cause severe reactions, the U.S. Food and Drug Administration (FDA) has been working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.

The principal differences between this edition and the 1989 edition are as follows:

(a) The maximum length for all catheter types is no longer specified.

(b) It is not mandatory for the balloon, where present, to remain essentially symmetrical, although excessive asymmetry may affect flow rates.

(c) Minimum lengths for all catheter types are now specified.

(d) Type III catheters have been introduced.

(e) Therapeutic Goods Order—General requirements for labels for therapeutic devices, has been called up for marking requirements.

(f) Catheters may be sterile or non-sterile.

(g) Requirements for 6 French gauge have been included.

(h) The test for cytotoxicity, as given in Appendix B, is a suggested acceptable method. The method itself is not mandatory, but if used, freedom from toxicity to the level required in the Appendix is a mandatory requirement.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard, whereas an 'informative' appendix is only for information and guidance.

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