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Australian Standard™

Instrumentation for use in association with non-active surgical implants—General requirements

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This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 21 May 2003 and published on 30 June 2003.

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Australian Standard™

Instrumentation for use in association with non-active surgical implants—General requirements

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committee HE-012, Surgical Implants. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/ New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 16061:2000, *Instrumentation for use in association with non-active surgical implants—General requirements.*

The objective of this Standard is to specify general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are resupplied after refurbishment.

The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

As this Standard is reproduced from an international Standard, the following applies:

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11135	Medical devices—Validation and routine control of ethylene oxide sterilization	11135	Medical devices—Validation and routine control of ethylene oxide sterilization
11137	Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization	11137	Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization
14155	Clinical investigation of medical devices	14155	Clinical investigation of medical devices
Reference to European Standard		*Australian Standard*	
EN		AS EN	
556	Sterilization of medical devices—Requirements for terminally sterilized medical devices to be labelled 'STERILE'	556	Sterilization of medical devices—Requirements for medical devices to be designated [STERILE]
		556.1	Part 1: Requirements for terminally sterilized medical devices

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