



## Scope of Accreditation

### Therapeutic Goods Administration

Site

#### Laboratories Branch Biomaterials & Engineering – Biomaterials & Engineering

Accreditation No.	Site No.	Date of Accreditation
2432	2425	10 Aug 1988

Address	Contact	Availability
136 Narrabundah Lane Symonston, ACT 2609 Australia <a href="http://tga.gov.au">tga.gov.au</a>	<span style="background-color: black; color: red;">s22</span> P <span style="background-color: black; color: red;">s22</span> TGA.Laboratories.Quality.System@health.gov.au	Services conditionally available to external clients

#### Laboratories Branch Biomaterials & Engineering – Biomaterials & Engineering

##### ISO/IEC 17025 (2017)

Manufactured Goods

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
Performance evaluation of healthcare equipment and related items	Examination gloves	Dimensions; Evaluation of consumer information - Labelling and markings; Leakage; Tensile properties; Visual examination	Not applicable	AS/NZS 4011.1 Parts 6.1, 6.2, 6.3 and 8, AS/NZS 4011.2 Parts 6.1, 6.2, 6.3 and 8
	Male condoms	Burst pressure; Burst volume; Evaluation of consumer information - Labelling and markings; Freedom from holes; Leakage; Length; Package integrity; Thickness; Total lubricant; Visible defects; Width	Not applicable	ISO 4074 Annexes A, C, D, E, F, H, I, M and N

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
Performance evaluation of personal protective equipment (PPE)	Medical face masks	Synthetic blood penetration	Not applicable	ISO 22609, in-house method BIOME - SOP - Medical Face Masks - Resistance against penetration by synthetic blood

The only data displayed is that deemed relevant and necessary for the clear description of the activities and services covered by the scope of accreditation.

Grey text appearing in a SoA is additional freetext providing further refinement or information on the data in the preceding line entry.

Accreditation No.	Site No.	Print date
2432	2425	11 Oct 2021

END OF SCOPE

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