

Operation	BiomE - Laboratory Operations Manual
Procedure	BiomE Competency - Authorisation Matrix
Written	8/22
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BiomE Competency / Authorisation Matrix

Procedure TRIM REF	Procedure Name	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22	8/22
	BIOME - Approver Authorisation of NATA Accredited Testing	✓	✓															
	BIOME - Authorisation for Approver of General Testing	✓	✓															
D17-937303	BIOME - SOP - Latex Condoms				✓			✓		✓								
D18-11165317	BIOME - SOP - Invasive blood pressure transducer testing					✓					✓							
D21-2002630	BIOME - SOP - Medical Face Masks - Measurement of Cannulas			✓											✓			
D20-3958656	SOP - BIOME - Particulate Penetration Efficiency Assessment – Rapid Screening					✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D20-3954795	BIOME - SOP - Medical Face Masks - Resistance against penetration by synthetic blood					✓		✓	✓	✓	✓		✓	✓	✓	✓		
D20-3454567	BIOME - SOP- Visual Inspection of Particle Filtering Respirators and Medical masks test				✓	✓	✓	✓	✓	✓			✓	✓	✓	✓		
D20-1026584	BIOME - SOP - Auto-Injector Pens - Single use medicine administration systems					✓												
D20-946139	BIOME - SOP - Receiving and registering Masks and preparing TRIMS containers				✓													
R16/268450	BIOME - SOP - Medical Examination Gloves				✓			✓		✓								
D18-10093469	BIOME - SOP - FlowCAM analysis of Particle extract solutions				✓													
D17-3500202	BIOME - SOP - Sampling and Filtration of Particle extract solutions				✓			✓										
D17-609267	BIOME - SOP - Sample Preparation and Extraction of Medical Devices to ISO 10993-12							✓	✓			✓		✓				
D19-6271776	BIOME - SOP - MTT assay - Cytotoxicity Testing of Medical Devices to ISO 10993-5							✓	✓			✓		✓				
D19-5239149	BIOME - SOP - Storage and Resuscitation of Cell Lines							✓	✓			✓		✓				
D19-5239157	BIOME - SOP - Subculture of Cell Lines							✓	✓		✓	✓		✓			✓	
D17-656589	BIOME - SOP - High potential insulation testing																	
D17-631553	BIOME - SOP - Handling, Decontamination, Storage and Disposal of Contaminated Devices							✓	✓									
D17-525636	BIOME - SOP - Use and development of in-house software					✓												
D19-5239131	BIOME - SOP - Cleaning, Washing, Sterilisation, Decontamination and Waste Disposal							✓	✓			✓		✓				
D17-120373	BIOME - SOP - Laundering Laboratory Gowns							✓	✓			✓		✓				
R16/947900	BIOME - SOP - Ventilator testing Accuracy of paediatric ventilation																	
D19-5239159	BIOME - SOP - Direct Contact and Agar Diffusion Tests - Cytotoxicity Testing of Medical Devices to ISO 10993-5							✓	✓			✓						
D19-5239160	BIOME - SOP - Elution Test - Cytotoxicity Testing of Medical Devices to ISO 10993-5							✓	✓			✓						
D19-5239164	BIOME - SOP - Contamination in Cell Cultures							✓	✓			✓		✓				
D19-5239172	BIOME - SOP - Cell Counting							✓	✓		✓	✓		✓			✓	
R16/639107	BIOME - SOP - Ventilator GUI Testing																	
R16/158790	BIOME - SOP - Testing of Needle-based Injection Systems to ISO 11608				✓			✓			✓							
R15/831856	BIOME - SOP - AED testing																	
R15/780280	BIOME - SOP - Examination - Breast implants				✓			✓										
R15/804340	BIOME - SOP - Microwaveable Heat Packs (Wheat Bag) testing to AS-NZS 5116									✓								
2011/004699	BIOME - SOP - Surface Tension Testing of Synthetic Blood				✓						✓				✓			