No	Testing		Reference Standard	Cost (RM)	Cost (USD)	Timeline
1	510k		ASTM	93,568.00	21,760.00	4 months
2	Biocompatiblity	Skin Sensitization	**ISO 10993-10: 2021** Biological Evaluation of Medical devices – Part 10: Test for Skin Sensitization	8,000.00	1,860.47	3 months
3		Irritation	**ISO 10993-23: 2021** Biological evaluation of medical devices. Part 23: Tests for irritation	2,684.00	624.19	3 months
4		In-vitro Cytotoxicity	**ISO 10993-5: 2009** Biological Evaluation of Medical devices – Part 5: Tests for in vitro cytotoxicity	2,365.00	550.00	5 weeks
5		Acute Systemic Toxicity	**ISO 10993-11: 2017** Biological Evaluation of Medical devices – Part 11: Tests for Systemic Toxicity	4,730.00	1,100.00	2 months
7	Pyrogen		**ISO 10993-11: 2017** Biological Evaluation of Medical devices – Part 11: Tests for Systemic Toxicity	3,225.00	750.00	3 weeks
8	ASTM D6319	Waterleak	ASTM D5151	Internal		
		Dimension	ASTM D3767	Internal		
		Physical Properties	ASTM D412	Internal		
9	Shelf Life		**EN 455-4: 2009** Medical gloves for single use – Part 4: Requirements and testing for shelf life determination	Internal		
10	Dose Mapping		**EN ISO 11137-1:2015** Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices			
11	Bacteriostasis & Fungistasis		**EN ISO 11737-2:2020** Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process			
12	Dose Audit (Product Sterility Test)					
13	Chemotheraphy		ASTM D6978	48,043.90	11,173.00	2 months
No	**Document**		**Reference Standard**			
1	Risk Management		**ISO 14971: 2019** Medical Devices – Application of Risk Management to Medical Devices	Internal	Internal	
				Total :	162,615.90	37,817.65