No	Medical Device	BRAND	ESTABLISHMENT NAME	MD REGISTRATION NO	Complaint	Test	Reference Standard	Summary of Result	Supported/ Not Supported
1	**TRANSFER SET**	Peritone Youwei / Lucenxia Transflo	ADVENTA HEALTHCARE SDN. BHD.	GA84078400417	Leakage at twist clamp during use.	**Hypothesis 1: Micro-tear at tubing**			
						Test 1: Fluid leakage	ECRI Test Method	Leakage at twist clamp due to degradation of silicone tubing from prolong exposure to Povidone Iodine	**SUPPORTED**
						Hypothesis 2: Insufficient connector bond strength			
						Test 1: Static Tensile 15N for 15s	ISO 80369	No detachment of tubing from connectors	Not Supported
						Hypothesis 3: Poor mechanical properties of tubing			
						Test 1: Tensile	ISO 10555-1	Good elastic properties were observed	Not Supported
						Hypothesis 4: Material composition causing defect			
						Test 1: Fourier Transform Infrared (FTIR)	ECRI Test Method	No tubing material degradation	Not Supported
						Hypothesis 5: Kinking induced tubing leakage			
						Test 1: Kink	ECRI Test Method	No impact on flow rate	Not Supported
						Hypothesis 6: Material fatigue from repeated clamping			
						Test 1: Repeated fatigue from repeated clamping	ECRI Test Method	No tubing leak	Not Supported
						Additional findings			
						Test 1: Visual inspection on MiniCap	ECRI Test Method	Crack on MiniCap	Not Applicable
						Test 2: Visual inspection on tubing	ECRI Test Method	Blockage of flow	Not Applicable
2	SCALPEL BLADE	Connecx-Surgimecx	ADVENTA HEALTHCARE SDN. BHD.	GB4223221-80686	Scalpel blades become blunt mid-procedure	**Hypothesis 1: Poor material quality**			
						Test 1: FESEM	ECRI Test Method	No contamination on blade surface	Not Supported
						Test 2: EDX	ECRI Test Method	Presence of typical metallic elements	
						Hypothesis 2: Excessive bending or cosmetic defects			
						Test 1: Microscopic inspection	ECRI Test Method	No bending or other cosmetic defects found	Not Supported
						Hypothesis 3: Surface contamination			
						Test 1: Fourier Transform Infrared (FTIR)	ECRI Test Method	No distinct peak from FTIR	Not Supported
						Additional Finding 1: Simulation of scalpel blade (Incorrect cutting technique & unable to cut test medium)			
		Paramount	M.I. MEDICAL SUPPLIES SDN BHD	GB7766625-199131		Test 1: Cutting technique & ability to cut a medium	ECRI Test Method	Product testing does not reveal any defects	Not supported
						Additional Finding 2: Corrosion from exposure to local anesthetics & bodily fluids			
						Literature review	N/A	Corrosion highly affects incising capability of scalpel blades & increases the risk of tissue trauma	**SUPPORTED**
						Additional Finding 3: Lack of coating on blade surface			
						Literature review	N/A	Accelerating the blunt process & increases tissue resistance	**SUPPORTED**
3	Hypromellose Eye Drop	Ain Medicare's Ophthal Mellose Eye Drop Solution	AIN MEDICARE SDN BHD	GB5836723-114988	Eye irritation, burning, allergic reactions	**Hypothesis 1: pH deviation**			
						Test 1: pH	USP <791>	Value within the human physiological pH tear range (6.5 to 7.6)	Not supported
						Hypothesis 2: Osmolality			
						Test 1: Osmolality	USP <785>	Value within the human physiological osmolality tear range (270 to 310 mOsm/kg)	Not supported
						Hypothesis 3: Leachable chemicals / chemical contamination			
						Test 1: Fourier Transform Infrared (FTIR)	ECRI Test Method	No contamination	Not supported
						Hypothesis 4: Compromised sterility			
						Test 1: Sterility	ECRI Test Method	No growth	Not supported
						Hypothesis 5: Endotoxin/pyrogen contamination			
						Test 1: Endotoxin	ECRI Test Method	Does not contain significant residual bacterial endotoxins	Not supported
						Hypothesis 6: Inappropriate Prescription			
						Test 1: Misapplication User Survey Analysis Data	ECRI Test Method	Survey results revealed clear prescribing patterns of Ain Ophthal Mellose Eye Drop to moderate to major eye trauma/injury patients, not adhering to its intended purpose of "for minor irritations"	**SUPPORTED**
						Hypothesis 7: Combined eye drop application			
						Test 1: Analysis of Co- Prescription Medication Survey Data	ECRI Test Method	Eye drop does not react with any of the medicine that are prescribed and used together	**SUPPORTED**
						Hypothesis 8: Cap Leak			
						Test 1: Cap Leak	ECRI Test Method	Demonstrated that the reclosable cap of the Ain Ophthal Mellose ampoule does not maintain an adequate seal after first opening	**SUPPORTED**
						Hypothesis 9: Compromised Cap Integrity			
						Test 1: Re-closable Cap Integrity	ECRI Test Method	Demonstrated defective opening mechanisms (poor tamper point scoring or incomplete severing) in Ain Ophthal Mellose ampoules	**SUPPORTED**

No	Medical Device	BRAND	ESTABLISHMENT NAME	MD REGISTRATION NO	Complaint	Test	Reference Standard	Summary of Result	Supported/ Not Supported
4	SURGICAL GLOVES	SURGEA surgical gloves (powdered)	AVECENA GLOVES SDN BHD	GB2884724-165273	Surgical gloves tears easily, contains excessive powder and causes allergies (rashes).	**Hypothesis 1: Additive in chemical formulation & degradation under high temperature**			
						Test 1: Tensile test	ASTM D3577	Exceeds minimum requirement of tensile strength	Not supported
						Test 2: Tensile strain	ISO 10282	Exceeds minimum requirement of tensile strain	Not supported
						Hypothesis 2: Elevated protein content levels			
						Test 1: Protein content	EN455-3	Passes protein content levels of below 50 µg/g	Not supported
						Hypothesis 3: Elevated powder content levels			
						Test 1: Powder content	ASTM D6124	Passes powder content levels of 15mg/dm2	Not supported
						Hypothesis 4: Donning & doffing			
						Test 1: Donning & doffing of glove	ECRI Test Method	No difficulty of donning & doffing	Not supported
						Hypothesis 5: Excessive appearance of powder			
						Test 1: Powder appearance after 30 minutes	ECRI Test Method	Granular powder appearance matches powder content quantitative testing	Not supported
5	HEMODIALYSIS CATHETER KIT	REAL FLOW hemodialysis catheter from Haolang Technology	ROCKY SCIENTIFIC INSTRUMENTATION	GB8127224-173483	Flow issues due to kinking of catheter and insertion difficulty	**Hypothesis 1: Stiffness of catheter body material**			
						Test 1: Tensile	ISO 10555-1	Real Flow Young's Modulus comparable with Mahurkar	Not Supported
						Hypothesis 2: Incompatible hospital disinfectant to the material			
						Test 1: Fourier Transform Infrared (FTIR)	ECRI Test Method	Silicone tubing is compatible with alcohol-based CHLOROHEXIDINE	Not Supported
						Hypothesis 3: Soft catheter tips cause bending leading to difficult penetration			
						Test 1: Tensile	ECRI Test Method	Real Flow catheter tip soft and easy to bend	**SUPPORTED**
						Hypothesis 4: Inconsistency in catheter's physical parameters			
						Test 1: Dimensional measurement of ID, OD and wall thickness	ECRI Test Method	Consistent wall thickness was observed	Not Supported
						Hypothesis 5: No coating on catheter surface			
						Test 1: Talcum powder	ECRI Test Method	Presence of coating on catheter surface	Not Supported
						Hypothesis 6: Catheter tip design led to difficult penetration			
						Test 1: Dimensional measurement of ID, OD and wall thickness	ECRI Test Method	Real Flow catheter tip wall thickness was thinner and shorter taper length compared to alternative brands	**SUPPORTED**
						Hypothesis 7: Catheter kinking			
						Test 1: Kink	ECRI Test Method	Real Flow flow reduction about 10% due to catheter kink	**SUPPORTED**
6	HEMODIALYSIS FLUID FILTER	BLT Biolight F210 fluid filters (Guang Dong Biolight Meditech Co., Ltd.)	VISION BIOMED SERVICES SDN.BHD	GB4794825-194066	Reduction in flow through heater, infection due to different membrane types enabling bacteria passage and leakage	**Hypothesis 1: Membrane pore size too large**			
						Test 1: FESEM	ECRI Test Method	DF220 has slightly larger pore size and pore area than DIASAFE® Plus but the differences are negligible.	Not Supported
						Hypothesis 2: Poor endotoxin retention capability			
						Test 1: Bacteria & Endotoxin Retention Analysis	ISO 23500-5:2024	Meets ISO 23500-5:2024 requirement. The total bacteria count (TBC) and endotoxin level are below <0.1CFU/ml and 0.03EU/ml.	Not Supported
						Hypothesis 3: Fluid filter connection incompatibility			
						Test 1: Functional Test & Inspection	ECRI Test Method	No leakage, machine alarms/ errors observed	Not Supported
						Hypothesis 4: Connector dimension mismatch			
						Test 1: Filter design & measurement	ECRI Test Method	Small differences in connectors, O-rings, and membrane thickness, with no sealing or leaking issues	Not Supported
						Additional findings: Technical specification			
						Test 1: Review of Data Sheet	ECRI Test Method	Noticeable difference in Transmembrane Pressure (TMP)	**SUPPORTED**