National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : ADGYL LIFESCIENCES PRIVATE LIMITED, 21 & 22, PHASE II, PEENYA INDUSTRIAL AREA, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-11008 **Page No** 1 of 3

Validity 24/09/2022 to 23/09/2024 **Last Amended on** -

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
Permanent Facility				
1	BIOLOGICAL-TOXICOLOGY	Contact Lenses, Lens Disinfecting and Cleaning Solutions	Acute Ocular Biocompatibility Test with Rabbit Eyes	ISO 9394
2	BIOLOGICAL-TOXICOLOGY	Contact Lenses, Lens Disinfecting and Cleaning Solutions	Cytotoxicity Test of Contact Lenses in Combination with Lens Care Solution	ISO 18189
3	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Cannula, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products	Tests for Interactions with Blood a. Hemolysis Test b. Complement Activation Test c. Coagulation Test	ISO 10993 (Part-4)
4	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Uterine Devices	Acute Intracutaneous (Intradermal) Reactivity Test in Rabbits	ISO 10993 (Part-23)
5	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Gloves, Condoms, Uterine Devices	In Vitro Cytotoxicity Test	ISO 10993 (Part-5)
6	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Gloves, Condoms, Uterine Devices	Acute Systemic Toxicity	ISO 10993 (Part-11)
7	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Gloves, Condoms, Uterine Devices	In Vitro Skin Corrosion	ISO 10993 (Part-23)
8	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Gloves, Condoms, Uterine Devices	In Vitro Skin Irritation	ISO 10993 (Part-23)

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9	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Gloves, Condoms, Uterine Devices	In Vitro Skin Sensitization	ISO 10993 (Part-10)
10	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Gloves, Condoms, Uterine Devices	Material Mediated Pyrogenicity in Rabbits	ISO 10993 (Part-11)
11	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Gloves, Condoms, Uterine Devices	Mucous Membrane Irritation Test	ISO 10993 (Part- 23)
12	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Gloves, Condoms, Uterine Devices	Skin Sensitization	ISO 10993 (Part-10)
13	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Uterine Devices	Bacterial Reverse Mutation Test	ISO 10993 (Part- 3)
14	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Uterine Devices	In Vitro Mammalian Cell Gene Mutation Test Using the Thymidine Kinase Gene	ISO 10993 (Part- 3)
15	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Uterine Devices	In Vitro Mammalian Cell Micronucleus Test	ISO 10993 (Part- 3)
16	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Uterine Devices	In Vitro Mammalian Chromosomal Aberration Test in CHO Cells	ISO 10993 (Part- 3)

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17	BIOLOGICAL-TOXICOLOGY	Disposable Perfusion Sets, Bag for Blood Storage, Cardiac Stents, Drug Eluting Stents, Catheters, Ocular Lenses, Cannula, Bone Cements, Artificial Heart Valves, Scalp Vein Set, Wound Suture and Closure Products, Wound Care Products, Peritoneal Dialysis Sets, Uterine Devices	In Vitro Mammalian Chromosomal Aberration Test in Human Peripheral Blood Lymphocytes	ISO 10993 (Part-3)
18	BIOLOGICAL-TOXICOLOGY	Wound Suture and Closure Products, Wound Care Products, Gloves	Skin Irritation Test in Rabbits	ISO 10993 (Part-23)