

Laboratory **Eurofins Advinus Limited, Plot No. 21 & 22, Phase 2, Peenya Industrial Area, Bengaluru, Karnataka**

Accreditation Standard **ISO/IEC 17025: 2005**

Certificate Number **TC-6864**

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Validity **07.02.2018 to 06.02.2020**

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
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BIOLOGICAL TESTING

I.	TOXICOLOGY			
1.	Medical devices (Disposable Perfusion Sets, Blood Bags, Cardiac Stents, Drug Eluting Stents, Catheters, Intra Ocular Lenses, I.V. Cannula, Bone Cements, heart valves, Scalp Vein Set, Internal Prosthetic Replacements, Wound suture and closure products, Peritoneal dialysis sets)	Bacterial Reverse Mutation Test	ISO 10993-3	Qualitative
		<i>In Vitro</i> Mammalian Chromosomal Aberration Test in CHO Cells	ISO 10993-3	Qualitative
		<i>In Vitro</i> Mammalian Cell Gene Mutation Test Using the Thymidine Kinase Gene	ISO 10993-3	Qualitative
		<i>In Vitro</i> Mammalian Chromosomal Aberration Test in Human Peripheral Blood Lymphocytes	ISO 10993-3	Qualitative
		<i>In Vitro</i> Mammalian Cell Micronucleus Test	ISO 10993-3	Qualitative
		Acute systemic toxicity	ISO 10993-11	Qualitative
		<i>In Vivo</i> Pyrogenicity	ISO 10993-11	Qualitative
2.	Biomaterials [Metals, polymers like Nylon, Polyvinyl Chloride, Polyethylene (linear), Polystyrene, Polypropylene, Fluorocarbon	Skin irritation tests in rabbits	ISO 10993-10	Qualitative
		Intracutaneous (intradermal) reactivity test in rabbits	ISO 10993-10	Qualitative
		Skin sensitization in guinea pigs	ISO 10993-10	Qualitative
		Tests for interactions with blood	ISO 10993-4	Qualitative
		<i>In vitro</i> cytotoxicity test	ISO 10993-5	Qualitative

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	Resins, Polyurethane, Acrylate Resins, Polyesters]			
3	Ophthalmic devices (Contact Lenses, Lens Disinfecting and Cleaning Solutions)	Ocular biocompatibility test with rabbit eyes	ISO 9394	Qualitative
		Cytotoxicity test of contact lenses in combination with lens care solution	ISO 18189	Qualitative