

NABL ACCREDITED LABORATORIES FOR MEDICAL DEVICES (BIOLOGICAL TESTS) AS PER ISO 10993 (VARIOUS PARTS)

STATE: KARNATAKA

- 1) Bionees India Private Limited, Devarahosahally, Sompura Hobli, Nelamangala Taluk, Bangalore Rural District Karnataka
Contact details: bionees@bionees.in Mr. Raghavendra N. Ph.0816-214400

S. No.	Product	Standard	Test
1	Toxicology Electrodes, External prostheses, Fixation tapes, Compression bandages, Probes of monitors of various types like ECG, blood pressure, Wound dressing materials, Contact lenses, Urinary catheters, Intravaginal and intra-intestinal devices, Endotracheal tubes, Bronchoscopes, Dental prostheses, Orthodontic devices, Dressings or healing devices, Occlusive patches for ulcers, burns and granulation tissue, Solution administration sets, extension sets, transfer sets and blood administration sets, Laparoscopes, Arthroscopes, draining systems, Dental cements, Dental filling materials, Skin staples, Intravascular catheters, Temporary pacemaker electrodes, Oxygenators, Extracorporeal oxygenator tubing and accessories, Dialysers, dialysis tubing and accessories, Haemoadsorbents and immunoadsorbents, Orthopaedic pins, plates, replacement joints, Bone prostheses, Bone cements, Intra-osseous devices, Pacemakers, Drug supply devices, Neuromuscular sensors and simulators, Replacement tendons, Breast implants, Artificial larynxes, Subperiosteal implants, Ligation clips and intra-uterine devices, Pacemaker electrodes, Artificial arteriovenous fistulae, Heart valves, vascular grafts, Internal drug-delivery catheters and ventricular assist devices, Stunts, Corneal Storage Media, Gels, Ophthalmic solutions, Scalpels, Gloves, Cochlear Implant, Condoms IUD and HIUD, Haemostat, Bioresorbable cardiac stent system, Bioresorbable Bare Metal cardiac stent system, Barrier Cream, Hernia Mesh, Respules, Rubber cork, Sutures, Needles	<p>ISO 10993-5 ISO 10993-12</p> <p>ISO 10993-11</p> <p>ISO 10993-10</p> <p>ISO 10993-3 ISO 10993-33 ISO 10993-12</p> <p>ISO 10993-4</p> <p>ISO 10993-10</p> <p>ISO 10993-11</p>	<p>Cytotoxicity Test: Elution method Agar overlay assay Direct contact assay NRU Cytotoxicity MTT Cytotoxicity</p> <p>Acute Systemic Toxicity Test</p> <p>Irritation Test</p> <p>Genotoxicity Test: Bacterial reverse mutation test In vitro mammalian chromosome aberration test In vitro mammalian- micronucleus test Mouse Lymphoma gene assay</p> <p>Hemocompatibility Test</p> <p>Skin Sensitization test</p> <p>Material Mediated Pyrogenicity in Rabbits</p>

- 2) Liveon Biolbs Pvt. Ltd., plot no. 46 & 47, II Phase, Water Tank Road, Kiadb Industrial Area, Antharasanahalli, Tumkur, Karnataka
 Contact Details: jyothi@liveonbiolabs.com Ms. Jyoti 9480849735

S. No.	Product	Standard	Test
1	Gloves, catheters, bronchoscope, solution & blood administration set, transfusion set, drainage set, oxygenator, extracorporeal oxygenator tubing and accessories, drug delivery catheters, sutures, needles	ISO 10993-5 ISO 10993-3 ISO 10993-10 ISO 10933-4 ISO 10993-11	Cytotoxicity Test, Elution method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity Genotoxicity Test, In Vitro -CHO Cell lines/In Vivo Chromosomal Aberration Test, Bacterial Reverse Mutation Test (Ames Test) In Vitro Chromosomal Aberration Test in Human Peripheral Blood Lymphocytes, In Vitro -CHO Cell lines/In Vivo Micronucleus Test, In Vitro Mammalian Cell Gene Mutation Test Using the Thymidine Kinase Gene Irritation Test , Primary Skin irritation Test and Intracutaneous Reactivity Test, Skin Sensitization Test - Guinea Pig Maximization Test, Buehler Test and Local Lymph Node Assay Interaction with blood Bacterial endotoxin test

- 3) Radiant Research Services Private Limited, 99/A, 8th Main, 3rd Phase, Peenya Industrial Area, Bangalore
 Contact Details: qms@radiantresearch.in Dr. Manjunath S Ph. 9449169172

S. No.	Product	Standard	Test
1	Medical Devices (Disposable Perfusion Sets, I.V. Cannula, Blood bags, Wound Suture And Closure Products, Peritoneal Dialysis Sets, Scalp Vein, Infusion tube, Stents, Catheters, Intra Ocular Lenses, Gels, Heart Valves, Gloves, Wound Dressing Materials, Intra-vaginal and inta-intestinal devices, Orthodontic Devices, Dental Prosthesis, Dental Filling Materials)	ISO 10993 -11 ISO 10993- 10 ISO 10993 – 11 & ISO 10993 – 12 ISO 10993 – 05 & ISO 10993- 12	Acute systemic toxicity Skin irritation, eye irritation, skin sensitization Material mediated pyrogenicity Cytotoxicity test, NRU cytotoxicity, MTT cytotoxicity

STATE: DELHI

- 4) Shriram Institute for Industrial Research (A Unit of Shriram Scientific & Industrial Research Foundation), 19, University Road, Delhi
Contact Details: laxmirawat@shriraminstitute.org Ph. 9818193810/08447705730 Dr. Laxmi Rawat

S. No.	Product	Standard	Test
1	Surface Device Skin Electrodes, External Protheses, Fixation Tapes, Compression Bandages, Monitors of Various Types	ISO-10993-5 ISO 10993- 10	Cytotoxicity Irritation / Intracutaneous reactivity
2	Mucosal Membrane Contact Devices, Endotracheal Tubes, Bronchoscopes	ISO 10993-5 ISO 10993-10 ISO 10993-3	Cytotoxicity Irritation, Intracutaneous reactivity Genotoxicity
3	Blood Path, Indirect: Solution Administration Sets, Extension Sets, Transfer Sets, Blood Admin Sets	ISO 10993-5 ISO 10993-10 ISO 10993-11,12 ISO 10993-3 ISO 10993-4	Cytotoxicity Irritation, Intracutaneous reactivity Systemic toxicity(Acute/short term) Carcinogenicity, Genotoxicity Haemolytic Properties of Material Haemo-compatibility test
4	Circulating Blood: Intravascular catheters, Temporary pacemaker electrodes, Oxygenators, Extracorporeal oxygenator Tubing and accessories	ISO 10993-5 ISO 10993-10 ISO 10993-11,12 ISO 10993-3 ISO 10993-4	Cytotoxicity Irritation, Intracutaneous reactivity Systemic toxicity(Acute/short term) Carcinogenicity, Genotoxicity Haemolytic Properties of Material Haemo-compatibility test

STATE: TAMIL NADU

- 5) Vanta Bioscience Limited, K2b, 11th Cross Street, Sipcot Industrial Complex, Gummidipoondi, Thiruvallur, Tamil Nadu
Contact Details: deepak.sharma@vantabio.com Mr. Deepak Sharma 9810299809

S. No.	Product	Standard	Test
1	Elbow Length Gloves, Powder free(PC), powder free sterile synthetic surgical gloves, powder free sterile surgical (micro) gloves, catheters,	ISO 10993	Skin sensitization, Cytotoxicity Test: Elution method, Agar overlay assay, Direct contact assay, NRU Cytotoxicity, irritation test

- 6) GLR Laboratories Private Limited, 444 Gokulam Street, Mathur, Chennai
Contact Details: Info@Glrlabs.Com Mr.K R Navaneethakrishnan Ph. 9841212596

S. No.	Product	Standard	Test
1	Gloves, Respiratory devices, tubes, catheters, bags	ISO 10993-10 ISO 10993-4 ISO 10993-11 ISO 10993-5	Intracutaneous test, skin irritation test, skin sensitization test Hemocompatibility, Hemolysis Acute Systemic toxicity, pyrogen Cytotoxicity

STATE: TELANGANA

- 7) Palamur Biosciences Private Limited, Sh-20, Karvina, Madigattla Village, Bhoothpur Mandal, Mahbubnagar, Telangana
Contact Details: 9492352676 vd.giridharrao@palamurbio.com Mr. V D Giridhar Rao

S. No.	Product	Standard	Test
1	Medical Devices (Surgical Gloves, Syringes with needles, Tubular Rings, Sutures, Surface devices, Catheters, External communicating devices)	ISO 10993-11 ISO 10993-6 ISO 10993-5 ISO 10993-10	Acute Systemic Toxicity, Pyrogenicity test Implantation Tests In vitro Cytotoxicity Skin sensitization test, Irritation (eye/ocular, skin), intracutaneous reactivity

STATE: GUJARAT

- 8) Accuprec Research Labs Pvt. Ltd., Opp. Zydus Pharmez, Changodar - Bavla Highway,, Ahmedabad
Contact Details : Rina.Gokani@Accuprec.Com Ms. Rina H. Gokani 9429571239

S. No.	Product	Standard	Test
1	Surgical gloves, Catheters, syringes with needles, Tubular rings, sutures, Intraocular implants, vascular devices and IV sets	ISO 10993-4 EN ISO 10993-11 ISO 10993-3 ISO 10993-5 ISO 10993-10	Hemocompatibility test, hemolysis test Pyrogen test, acute systemic toxicity Chromosomal aberration test, Ame's test, Micronucleus test Cytotoxicity MTT assay Eye irritation test, intracutaneous mucous membrane irritation test, skin sensitization test

STATE: UTTAR PRADESH

- 9) Institute for Industrial Research & Toxicology, F-209, Phase-1, U.P.S.I.D.C., Masuri Dhaulna, Gulawati Marg, Ghaziabad, Uttar Pradesh.
Contact Details: Ms.Shalini Mishra, iirtdelhi@gmail.com 9711623081

S. No.	Product	Standard	Test
1	Absorbent Cotton (Wound Surgical)	ISO 10993	Mucous membrane irritation test on Rabbit, Skin sensitization test on Guinea Pig,
	Acetabular Shell (Orthopedics)	ISO 10993	Mucous membrane irritation test on Rabbit, Skin sensitization test on Guinea Pig, Eye Irritation Test on Rabbit, Acute Toxicity dermal test on Mice, Acute Toxicity Dermal test on Rat, Acute Toxicity oral Test on Rat, Skin sensitization test on Guinea Pig,
	Bandages (Wound Surgical) Dialysis Tubing & Accessories (External Communicating device)	ISO 10993	Skin sensitization test on Guinea Pig,
	Face Mask (Surface Device)	ISO 10993	Eye irritation test on Rabbit
	Medical Device Invo Vac Foam Dressing	ISO 10993-10 ISO 10993-11	Acute Dermal Toxicity (RAT) Acute Oral Toxicity (Rat)
	Wound Protector (Wound Surgical)	ISO 10993	Skin sensitization test on Guinea Pig