



National Accreditation Board for
Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

**INTERNATIONAL INSTITUTE OF BIOTECHNOLOGY AND
TOXICOLOGY**

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

**"General Requirements for the Competence of Testing &
Calibration Laboratories"**

for its facilities at

3/266, BDO OFFICE ROAD, PADAPPAL, KANCHIPURAM, TAMIL NADU, INDIA

in the field of

TESTING

Certificate Number: TC-14684

Issue Date: 10/10/2024

Valid Until: 09/10/2028

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.
(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Entity: INTERNATIONAL INSTITUTE OF BIOTECHNOLOGY AND TOXICOLOGY

Signed for and on behalf of NABL



N. Venkateswaran
Chief Executive Officer



National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

| | | | |
|-------------------------------|--|------------------------|--------|
| Laboratory Name : | INTERNATIONAL INSTITUTE OF BIOTECHNOLOGY AND TOXICOLOGY, 3/266, BDO OFFICE ROAD, PADAPPALAI, KANCHIPURAM, TAMIL NADU, INDIA | | |
| Accreditation Standard | ISO/IEC 17025:2017 | | |
| Certificate Number | TC-14684 | Page No | 1 of 7 |
| Validity | 10/10/2024 to 09/10/2028 | 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 Testing | | |





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Certificate Number TC-14684 **Page No** 2 of 7

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|------|-----------------------|--|--|--|
| 1 | BIOLOGICAL-TOXICOLOGY | Ophthalmic Devices, Contact Lenses, Ophthalmic Solutions, Corneal Storage Media and Gels, Catheters, Guiding Catheters, Urinary Catheters, Intravascular Catheters, Internal Drug Delivery Catheters, Ventricular Assist Catheters, Bladder Catheters, Infusion Sets, Scalp Vein Sets, Transfusion Sets, Perfusion Catheters, Guide Wires, Cannula, Parenteral Nutrition Catheters, Central Venous Catheters, Natural Orifice Devices Intra vaginal Devices, Male and Female Condoms, Intra -Uterine Devices, Ligation Clips, Latex Oral Dams, Endotracheal Tubes Bronchoscope Dental, Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Wound Care Devices, Fixation Tapes, Compression Bandages, Wound Dressing Materials, Dressings or Healing Devices, Occlusive Patches for Ulcers, Burns, and Granulation tissue, Skin Staples, Solution Administration Sets, Extension Sets, Transfer Sets, Blood Administration Sets, Drug Supply Devices, IV Cannula, Laparoscopes, Arthroscopes, Draining System, Bronchoscopes, Laryngoscopes, Tubing used for Irrigation, Syringes, Blood Bags, Cardiovascular Devices Heart Lung Pack, Pacemakers, Heart Valves, Vascular Grafts, Cardiac Stents, Ventricular Assist Devices, Electrodes, Oxygenators, Extra Corporeal Oxygenators Tubing and Accessories, Dialysis Tubing and Accessories, Haem Absorbents, Immunosorbents, Lancets, Hypodermic Needles, Capillary Tubes, External Prostheses, External Communicating Devices, Respiratory Devices, Oxygenators, Extra Corporal Oxygenator Tubing and accessories Endo Tracheal Tubes, Feeding Tubes, Disposables, Needles, Face Mask, Gloves, PPE Implant Devices, Orthopaedic Pins, Plates, Replacement joints, Bone Prostheses, Bone Cements, Intra Osseous Device, Brest Implants, Sutures, Bioresorbable Bare Metal Cardiac Stent System, Spinal Implants, Cochlear Implant, Artificial Larynxes, Stunts, Hernia Mesh, Replacement Tendons, Ligation Clips, Cardiovascular Devices, Orthopaedic Implant | In vitro Cytotoxicity (Cell Lines - L929) | ISO 10993-5 |



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|------|-----------------------|--|--|--|
| 2 | BIOLOGICAL-TOXICOLOGY | Ophthalmic Devices, Contact Lenses, Ophthalmic Solutions, Corneal Storage Media and Gels, Catheters, Guiding Catheters, Urinary Catheters, Intravascular Catheters, Internal Drug Delivery Catheters, Ventricular Assist Catheters, Bladder Catheters, Infusion Sets, Scalp Vein Sets, Transfusion Sets, Perfusion Catheters, Guide Wires, Cannula, Parenteral Nutrition Catheters, Central Venous Catheters, Natural Orifice Devices Intra vaginal Devices, Male and Female Condoms, Intra -Uterine Devices, Ligation Clips, Latex Oral Dams, Endotracheal Tubes Bronchoscope Dental, Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Wound Care Devices, Fixation Tapes, Compression Bandages, Wound Dressing Materials, Dressings or Healing Devices, Occlusive Patches for Ulcers, Burns, and Granulation tissue, Skin Staples, Solution Administration Sets, Extension Sets, Transfer Sets, Blood Administration Sets, Drug Supply Devices, IV Cannula, Laparoscopes, Arthroscopes, Draining System, Bronchoscopes, Laryngoscopes, Tubing used for Irrigation, Syringes, Blood Bags, Cardiovascular Devices Heart Lung Pack, Pacemakers, Heart Valves, Vascular Grafts, Cardiac Stents, Ventricular Assist Devices, Electrodes, Oxygenators, Extra Corporeal Oxygenators Tubing and Accessories, Dialysis Tubing and Accessories, Haem Absorbents, Immunosorbents, Lancets, Hypodermic Needles, Capillary Tubes, External Prostheses, External Communicating Devices, Respiratory Devices, Oxygenators, Extra Corporal Oxygenator Tubing and accessories Endo Tracheal Tubes, Feeding Tubes, Disposables, Needles, Face Mask, Gloves, PPE Implant Devices, Orthopaedic Pins, Plates, Replacement joints, Bone Prostheses, Bone Cements, Intra Osseous Device, Brest Implants, Sutures, Bioresorbable Bare Metal Cardiac Stent System, Spinal Implants, Cochlear Implant, Artificial Larynxes, Stunts, Hernia Mesh, Replacement Tendons, Ligation Clips, Cardiovascular Devices, Orthopaedic Implant | Material Mediated Pyrogenicity in Rabbits | ISO 10993-11 |



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| 3 | BIOLOGICAL-TOXICOLOGY | Ophthalmic Devices, Contact Lenses, Ophthalmic Solutions, Corneal Storage Media and Gels, Catheters, Guiding Catheters, Urinary Catheters, Intravascular Catheters, Internal Drug Delivery Catheters, Ventricular Assist Catheters, Bladder Catheters, Infusion Sets, Scalp Vein Sets, Transfusion Sets, Perfusion Catheters, Guide Wires, Cannula, Parenteral Nutrition Catheters, Central Venous Catheters, Natural Orifice Devices, Intra vaginal Devices, Male and Female Condoms, Intra -Uterine Devices, Ligation Clips, Latex Oral Dams, Endotracheal Tubes, Bronchoscope Dental, Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Wound Care Devices, Fixation Tapes, Compression Bandages, Wound Dressing Materials, Dressings or Healing Devices, Occlusive Patches for Ulcers, Burns and Granulation Tissue, Skin Staples, Solution Administration Sets, Extension Sets, Transfer Sets, Blood Administration Sets, Drug Supply Devices, IV Cannula, Laparoscopes, Arthroscopes, Draining System, Bronchoscopes, Laryngoscopes, Tubing used for Irrigation, Syringes, Blood Bags, Cardiovascular Devices, Heart Lung Pack, Pacemakers, Heart Valves, Vascular Grafts, Cardiac Stents, Ventricular Assist Devices, Electrodes, Oxygenators, Extra Corporeal Oxygenators Tubing and Accessories, Dialysis Tubing and Accessories, Haem Absorbents, Immunosorbents, Lancets, Hypodermic Needles, Capillary Tubes, External Prostheses, External Communicating Devices, Respiratory Devices, Oxygenators, Extra Corporal Oxygenator Tubing and Accessories, Endo Tracheal Tubes, Feeding Tubes, Disposables Needles, Face Mask, Gloves, PPE, Implant Devices, Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Intra Osseous Device, Brest Implants, Sutures, Bioresorbable Bare Metal Cardiac Stent System, Spinal Implants, Cochlear Implant, Artificial Larynxes, Stunts, Hernia Mesh, Replacement Tendons, Ligation Clips, Cardiovascular Devices, Orthopaedic Implant | Irritation Test in Rabbits | ISO 10993-23 |



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| 4 | BIOLOGICAL-TOXICOLOGY | Ophthalmic Devices, Contact Lenses, Ophthalmic Solutions, Corneal Storage Media, and Gels Catheters, Guiding Catheters, Urinary Catheters, Intravascular Catheters, Internal Drug Delivery Catheters, Ventricular Assist Catheters, Bladder Catheters, Infusion Sets, Scalp Vein Sets, Transfusion Sets, Perfusion Catheters, Guide Wires, Cannula, Parenteral Nutrition Catheters, Central Venous Catheters, Natural Orifice Devices, Intra vaginal Devices, Male and Female Condoms, Intra -Uterine Devices, Ligation Clips, Latex Oral Dams Endotracheal Tubes, Bronchoscope Dental , Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Wound Care Devices, Fixation Tapes, Compression Bandages, Wound Dressing Materials, Dressings or Healing Devices, Occlusive Patches for Ulcers, Burns, and Granulation tissue, Skin staples, Solution Administration Sets, Extension Sets, Transfer Sets, Blood Administration Sets, Drug Supply Devices, IV Cannula, Laparoscopes, Arthroscopes, Draining System, Bronchoscopes, Laryngoscopes, Tubing used for Irrigation, Syringes, Blood Bags, Cardiovascular Devices, Heart Lung Pack, Pacemakers, Heart Valves, Vascular Grafts, Cardiac Stents, Ventricular Assist Devices, Electrodes, Oxygenators, Extra Corporeal Oxygenators Tubing and Accessories, Dialysis Tubing and Accessories, Haem Absorbents, Immunosorbents, Lancets, Hypodermic Needles, Capillary Tubes External Prostheses, External Communicating Devices Respiratory Devices, Oxygenators, Extra Corporal Oxygenator Tubing and accessories, Endo Tracheal Tubes, Feeding Tubes, Disposables, Needles, Face Mask, Gloves, PPE, Implant Devices, Orthopaedic Pins, Plates, Replacement joints, Bone Prostheses, Bone Cements, Intra Osseous Device, Brest Implants, Sutures, Bioresorbable Bare Metal Cardiac Stent System, Spinal Implants, Cochlear Implant, Artificial Larynxes, Stunts, Hernia Mesh, Replacement Tendons, Ligation Clips, Cardiovascular Devices, Orthopaedic Implant | Skin Sensitization in Guinea Pigs | ISO 10993-10 |



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| 5 | BIOLOGICAL-TOXICOLOGY | Ophthalmic Devices, Contact Lenses, Ophthalmic Solutions, Corneal Storage Media, and Gels, Catheters, Guiding Catheters, Urinary Catheters, Intravascular Catheters, Internal Drug Delivery Catheters, Ventricular Assist Catheters, Bladder Catheters, Infusion Sets, Scalp Vein Sets, Transfusion Sets, Perfusion Catheters, Guide Wires, Cannula, Parenteral Nutrition Catheters, Central Venous Catheters, Natural Orifice Devices Intra vaginal Devices, Male and Female Condoms, Intra -Uterine Devices, Ligation Clips, Latex Oral Dams, Endotracheal Tubes Bronchoscope Dental, Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Wound Care Devices, Fixation Tapes, Compression Bandages, Wound Dressing Materials, Dressings or Healing Devices, Occlusive Patches for Ulcers, Burns, and Granulation tissue, Skin staples, Solution Administration Sets, Extension Sets, Transfer Sets, Blood Administration Sets, Drug Supply Devices, IV Cannula, Laparoscopes, Arthroscopes, Draining System, Bronchoscopes, Laryngoscopes, Tubing used for Irrigation, Syringes, Blood Bags Cardiovascular Devices, Heart Lung Pack, Pacemakers, Heart Valves, Vascular Grafts, Cardiac Stents, Ventricular Assist Devices, Electrodes, Oxygenators, Extra Corporeal Oxygenators Tubing and Accessories, Dialysis Tubing and Accessories, Haem Absorbents, Immunosorbents, Lancets, Hypodermic Needles, Capillary Tubes, External Prostheses, External Communicating Devices Respiratory Devices, Oxygenators, Extra Corporal Oxygenator Tubing and accessories Endo Tracheal Tubes, Feeding Tubes Disposable Needles, Face Mask, Gloves, PPE Implant Devices, Orthopaedic Pins, Plates, Replacement joints, Bone Prostheses, Bone Cements, Intra Osseous Device, Brest Implants, Sutures, Bioresorbable Bare Metal Cardiac Stent System, Spinal Implants, Cochlear Implant, Artificial Larynxes, Stunts, Hernia Mesh, Replacement Tendons, Ligation Clips, Cardiovascular Devices, Orthopaedic Implant | Acute Systemic Toxicity in Rat and Mice | ISO 10993-11 |



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|------|-----------------------|---|--|--|
| 6 | BIOLOGICAL-TOXICOLOGY | Orthopaedic Pins, Plates, Replacement joints, Bone Prosthesis, Bone Cements, Intra Osseous Device, Breast Implants, Sutures, Bioresorbable Bare Metal Cardiac Stent System, Spinal Implants, Cochlear Implant, Artificial Larynxes, Stents, Hernia Mesh, Replacement Tendons, Ligation Clips, Cardiovascular Devices, Orthopaedic Implant | Local Effects after Implantation | ISO 10993-6 |