# National Accreditation Board for Testing and Calibration Laboratories

## SCOPE OF ACCREDITATION

**Laboratory Name :** ADITA BIOSYS PRIVATE LIMITED, PLOT NO. SPL 26, 2ND STAGE, KSSIDC INDUSTRIAL ESTATE, ANTHARASANAHALLI, MADHUGIRI ROAD, TUMKUR, KARNATAKA, INDIA

**Accreditation Standard** ISO/IEC 17025:2017

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**Validity** 19/10/2022 to 18/10/2024 **Last Amended on** -

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|---|---|---|---|---|
| Permanent Facility | | | | |
| 1 | BIOLOGICAL-TOXICOLOGY | Blood Bags | Cytotoxicity Test (Elution Method) | ISO 10993, Part-5, Page 6 |
| 2 | BIOLOGICAL-TOXICOLOGY | Blood Bags | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33, Page 3-10 |
| 3 | BIOLOGICAL-TOXICOLOGY | Blood Bags | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3, Page 4-7 |
| 4 | BIOLOGICAL-TOXICOLOGY | Blood Bags | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 5 | BIOLOGICAL-TOXICOLOGY | Blood Bags | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 6 | BIOLOGICAL-TOXICOLOGY | Cardiovascular Devices (Heart Valves) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 7 | BIOLOGICAL-TOXICOLOGY | Cardiovascular Devices (Heart Valves) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3, Page 4-7 |
| 8 | BIOLOGICAL-TOXICOLOGY | Cardiovascular Devices (Heart Valves) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33, Page 3-10 |
| 9 | BIOLOGICAL-TOXICOLOGY | Cardiovascular Devices (Heart Valves) | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11, Page 25 |
| 10 | BIOLOGICAL-TOXICOLOGY | Cardiovascular Devices (Heart Valves) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 11 | BIOLOGICAL-TOXICOLOGY | Dental (Orthodontic Devices) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 12 | BIOLOGICAL-TOXICOLOGY | Dental (Orthodontic Devices) | Cytotoxicity Test (Elution Method) | ISO 10993, Part-5, Page 6 |
| 13 | BIOLOGICAL-TOXICOLOGY | Dental (Orthodontic Devices) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 14 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 15 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Cytotoxicity Test (Elution Method) | ISO 10993, Part-5, Page 6 |
| 16 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3, Page 4-7 |
| 17 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33, Page 3-10 |
| 18 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11, Page 25 |

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| 19 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Genotoxicity Test: In Vivo Mammalian Micronucleus Test | ISO 10993, Part-3, Page 4-7 |
| 20 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Genotoxicity Test: In Vivo Mammalian Micronucleus Test | ISO 10993, Part-33, Page 32-38 |
| 21 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Skin Sensitization Test (Guinea Pig Maximization Test) | ISO 10993, Part-10, Page 11-15 |
| 22 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 23 | BIOLOGICAL-TOXICOLOGY | Disposables (Gloves) | Test of Irritation (Ocular) | ISO 10993, Part-23, Page 36 |
| 24 | BIOLOGICAL-TOXICOLOGY | Electrodes | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 25 | BIOLOGICAL-TOXICOLOGY | Electrodes | Cytotoxicity Test (Elution Method) | ISO 10993, Part-5, Page 6 |
| 26 | BIOLOGICAL-TOXICOLOGY | Electrodes | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 27 | BIOLOGICAL-TOXICOLOGY | External Communicating Devices (Extension Sets) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 28 | BIOLOGICAL-TOXICOLOGY | External Communicating Devices (Extension Sets) | Cytotoxicity Test (Direct Contact Assay) | ISO 10993, Part-5, Page 7 |
| 29 | BIOLOGICAL-TOXICOLOGY | External Communicating Devices (Extension Sets) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33, Page 3-10 |
| 30 | BIOLOGICAL-TOXICOLOGY | External Communicating Devices (Extension Sets) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3, Page 4-7 |
| 31 | BIOLOGICAL-TOXICOLOGY | External Communicating Devices (Extension Sets) | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11, Page 25 |
| 32 | BIOLOGICAL-TOXICOLOGY | External Communicating Devices (Extension Sets) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 33 | BIOLOGICAL-TOXICOLOGY | Hypodermic Needles | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 34 | BIOLOGICAL-TOXICOLOGY | Hypodermic Needles | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 35 | BIOLOGICAL-TOXICOLOGY | Hypodermic Needles | Genotoxicity Test: In Vivo Mammalian Chromosomal Aberration Test | ISO 10993, Part-33, Page 39-44 |
| 36 | BIOLOGICAL-TOXICOLOGY | Hypodermic Needles | Genotoxicity Test: In Vivo Mammalian Chromosomal Aberration Test | ISO 10993, Part-3, Page 4-7 |

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| 37 | BIOLOGICAL-TOXICOLOGY | Hypodermic Needles | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11, Page 25 |
| 38 | BIOLOGICAL-TOXICOLOGY | Hypodermic Needles | Skin Sensitization Test (Guinea Pig Maximization Test) | ISO 10993, Part-10, Page 11-15 |
| 39 | BIOLOGICAL-TOXICOLOGY | Implant Devices (Sutures) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 40 | BIOLOGICAL-TOXICOLOGY | Implant Devices (Sutures) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33, Page 3-10 |
| 41 | BIOLOGICAL-TOXICOLOGY | Implant Devices (Sutures) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3, Page 4-7 |
| 42 | BIOLOGICAL-TOXICOLOGY | Implant Devices (Sutures) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 43 | BIOLOGICAL-TOXICOLOGY | Intravascular Catheters | Cytotoxicity Test (Agar Overlay Assay) | ISO 10993, Part-5, Page 7 |
| 44 | BIOLOGICAL-TOXICOLOGY | Intravascular Catheters | Genotoxicity Test: In Vitro Mammalian Chromosomal Aberration Test | ISO 10993, Part-3, Page 4-7 |
| 45 | BIOLOGICAL-TOXICOLOGY | Intravascular Catheters | Genotoxicity Test: In Vitro Mammalian Chromosomal Aberration Test | ISO 10993, Part-33, Page 11-17 |
| 46 | BIOLOGICAL-TOXICOLOGY | Intravascular Catheters | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 47 | BIOLOGICAL-TOXICOLOGY | Intravascular Catheters | Skin Sensitization Test (Guinea Pig Maximization Test) | ISO 10993, Part-10, Page 11-15 |
| 48 | BIOLOGICAL-TOXICOLOGY | Intravascular Catheters | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 49 | BIOLOGICAL-TOXICOLOGY | Male Condoms | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 50 | BIOLOGICAL-TOXICOLOGY | Male Condoms | Cytotoxicity Test (Direct Contact Assay) | ISO 10993, Part-5, Page 7 |
| 51 | BIOLOGICAL-TOXICOLOGY | Male Condoms | Genotoxicity Test: In Vitro Mammalian Micronucleus Test | ISO 10993, Part-33, Page 17-24 |
| 52 | BIOLOGICAL-TOXICOLOGY | Male Condoms | Genotoxicity Test: In Vitro Mammalian Micronucleus Test | ISO 10993, Part-3, Page 4-7 |
| 53 | BIOLOGICAL-TOXICOLOGY | Male Condoms | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 54 | BIOLOGICAL-TOXICOLOGY | Male Condoms | Skin Sensitization Test (Guinea Pig Maximization Test) | ISO 10993, Part-10, Page 11-15 |

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|---|---|---|---|---|
| 55 | BIOLOGICAL-TOXICOLOGY | Natural Orifice Devices | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 56 | BIOLOGICAL-TOXICOLOGY | Natural Orifice Devices | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 57 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Contact Lens) | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11, Page 25 |
| 58 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Contact Lens) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 59 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Contact Lens) | Cytotoxicity Test (Agar Overlay Assay) | ISO 10993, Part-5, Page 7 |
| 60 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Contact Lens) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 61 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Genotoxicity Test: In Vitro and In Vivo Mammalian Micronucleus Test | ISO 10993, Part-3 |
| 62 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Genotoxicity Test: In Vitro and In Vivo Mammalian Micronucleus Test | ISO 10993, Part-33 |
| 63 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33 |
| 64 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Cytotoxicity Test (Elution Method, Agar Overlay Assay, Direct Contact Assay) | ISO 10993, Part-5 |
| 65 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Genotoxicity Test: In Vitro and In Vivo Mammalian Chromosomal Aberration Test | ISO 10993, Part-3 |
| 66 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3 |
| 67 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Genotoxicity Test: In Vitro and In Vivo Mammalian Chromosomal Aberration Test | ISO 10993, Part-33 |
| 68 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11 |
| 69 | BIOLOGICAL-TOXICOLOGY | Ophthalmic (Ophthalmic Solutions) | Test of Irritation (Intracutaneous, Dermal Penile, Vaginal) | ISO 10993, Part-23 |
| 70 | BIOLOGICAL-TOXICOLOGY | Orthopaedic Devices (Bone Cement) | Genotoxicity Test: In Vivo Mammalian Micronucleus Test | ISO 10993, Part-3, Page 4-7 |
| 71 | BIOLOGICAL-TOXICOLOGY | Orthopaedic Devices (Bone Cement) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |

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| 72 | BIOLOGICAL-TOXICOLOGY | Orthopaedic Devices (Bone Cement) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 73 | BIOLOGICAL-TOXICOLOGY | Orthopaedic Devices (Bone Cement) | Genotoxicity Test: In Vivo Mammalian Micronucleus Test | ISO 10993, Part-33, Page 32-38 |
| 74 | BIOLOGICAL-TOXICOLOGY | Orthopaedic Devices (Bone Cement) | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11, Page 25 |
| 75 | BIOLOGICAL-TOXICOLOGY | Respiratory Devices (Endotracheal Tube) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 76 | BIOLOGICAL-TOXICOLOGY | Respiratory Devices (Endotracheal Tube) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3, Page 4-7 |
| 77 | BIOLOGICAL-TOXICOLOGY | Respiratory Devices (Endotracheal Tube) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33, Page 3-10 |
| 78 | BIOLOGICAL-TOXICOLOGY | Respiratory Devices (Endotracheal Tube) | Skin Sensitization Test (Guinea Pig Maximization Test) | ISO 10993, Part-10, Page 11-15 |
| 79 | BIOLOGICAL-TOXICOLOGY | Respiratory Devices (Endotracheal Tube) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 80 | BIOLOGICAL-TOXICOLOGY | Scopes (Laryngoscope) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 81 | BIOLOGICAL-TOXICOLOGY | Scopes (Laryngoscope) | Cytotoxicity Test (Elution Method) | ISO 10993, Part-5, Page 6 |
| 82 | BIOLOGICAL-TOXICOLOGY | Scopes (Laryngoscope) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3, Page 4-7 |
| 83 | BIOLOGICAL-TOXICOLOGY | Scopes (Laryngoscope) | Skin Sensitization Test (Guinea Pig Maximization Test) | ISO 10993, Part-10, Page 11-15 |
| 84 | BIOLOGICAL-TOXICOLOGY | Scopes (Laryngoscope) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33, Page 3-10 |
| 85 | BIOLOGICAL-TOXICOLOGY | Scopes (Laryngoscope) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 86 | BIOLOGICAL-TOXICOLOGY | Surgical Instruments (Surgical Blade) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 87 | BIOLOGICAL-TOXICOLOGY | Surgical Instruments (Surgical Blade) | Genotoxicity Test: In Vitro Mammalian Micronucleus Test | ISO 10993, Part-3, Page 4-7 |
| 88 | BIOLOGICAL-TOXICOLOGY | Surgical Instruments (Surgical Blade) | Genotoxicity Test: In Vitro Mammalian Micronucleus Test | ISO 10993, Part-33, Page 17-24 |
| 89 | BIOLOGICAL-TOXICOLOGY | Surgical Instruments (Surgical Blade) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 36 |
| 90 | BIOLOGICAL-TOXICOLOGY | Surgical Instruments (Surgical Blade) | Cytotoxicity Test (Elution Method) | ISO 10993, Part-5, Page 6 |

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| 91 | BIOLOGICAL-TOXICOLOGY | Surgical Instruments (Surgical Blade) | Skin Sensitization Test (Guinea Pig Maximization Test) | ISO 10993, Part-10, Page 11-15 |
| 92 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Surgical Tape) | Genotoxicity Test: In Vitro Mammalian Chromosomal Aberration Test | ISO 10993, Part-33, Page 11-17 |
| 93 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Surgical Tape) | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11, Page 25 |
| 94 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Surgical Tape) | Test of Irritation (Intracutaneous) | ISO 10993, Part-23, Page 21-25 |
| 95 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Surgical Tape) | Acute Systemic Toxicity Test | ISO 10993, Part-11, Page 7-12 |
| 96 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Surgical Tape) | Genotoxicity Test: In Vitro Mammalian Chromosomal Aberration Test | ISO 10993, Part-3, Page 4-7 |
| 97 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Genotoxicity Test: In Vitro and In Vivo Mammalian Chromosomal Aberration Test | ISO 10993, Part-3 |
| 98 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Genotoxicity Test: In Vitro and In Vivo Mammalian Chromosomal Aberration Test | ISO 10993, Part-33 |
| 99 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Genotoxicity Test: In Vitro and In Vivo Mammalian Micronucleus Test | ISO 10993, Part-3 |
| 100 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Genotoxicity Test: In Vitro and In Vivo Mammalian Micronucleus Test | ISO 10993, Part-33 |
| 101 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-3 |
| 102 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Test of Irritation (Intracutaneous, Dermal, Oral, Penile, Vaginal and Rectal) | ISO 10993, Part-23 |
| 103 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Cytotoxicity Test (Elution Method, Agar Overlay Assay and Direct Contact Assay) | ISO 10993, Part-5 |
| 104 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Genotoxicity Test: Bacterial Reverse Mutation Test | ISO 10993, Part-33 |
| 105 | BIOLOGICAL-TOXICOLOGY | Wound Care Devices (Wound Dressing Materials, Dressings or Healing Devices) | Material Mediated Pyrogenicity in Rabbits | ISO 10993, Part-11 |