National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : GLR LABORATORIES PRIVATE LIMITED, 444 GOKULAM STREET, MATHUR, CHENNAI, TAMIL NADU, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6251 **Page No** 1 of 11

Validity 03/10/2021 to 02/10/2023 **Last Amended on** 08/11/2021

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	Ocular devices: Intraocular lens, implements, eye drops, containers.	Eye Irritation Test	GLR Validated SOP TOX-027
2	BIOLOGICAL-TOXICOLOGY	Ocular devices: Intraocular lens, implements, eye drops, containers.	Eye Irritation Test	ISO 10993-10
3	BIOLOGICAL-TOXICOLOGY	Ocular devices: Intraocular lens, implements, eye drops, containers.	Eye Irritation Test	Schedule Y, Drug and Cosmetics Amd.2 rules
4	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers.	Abnormal Toxicity	USP 43 (88)
5	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers.	Hemocompatibility	ISO 10993-4

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6	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers.	Hemolysis	ASTM F 756
7	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers.	Hemolysis	ISO 10993-4

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8	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers.	Hemolysis	ISO 3826-1
9	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers.	Skin Irritation Test	GLR Validated SOP TOX-015

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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
10	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers.	Skin Irritation Test	ISO 10993-10
11	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Acute Systemic Toxicity	ISO 10993-11

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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
12	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Cytotoxicity	ISO 10993-5
13	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Cytotoxicity	USP 43 (87)

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14	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Pyrogen	ISO 10993-11
15	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Pyrogen	USP 43 (151)

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16	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Skin Sensitization Test	GLR Validated SOP TOX-011 and SOP TOX-040
17	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Skin Sensitization Test	GLR Validated SOP TOX-041, SOP TOX-042 and SOP TOX-043

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18	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Skin Sensitization Test	ISO 10993-10
19	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Skin Sensitization Test	Schedule Y Drug and Cosmetics Amd.2 rules

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20	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers.	Skin Irritation Test	Schedule Y Drug and Cosmetics Amd.2 rules
21	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Acute Systemic Toxicity	USP 43 (88)

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22	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Intracutaneous Test	ISO 10993-10
23	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents, wires, bags, filters, tubes. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Blades, needles, surgical implements, electrodes, sutures, mesh; staplers. Respiratory devices: Tubes, catheters, bags. Gastrointestinal devices: Tubes, catheters, bags, scopes. Paediatrics: Tubes, catheters, electrodes, incubator station. Neurological: Implements, electrodes, wires, needles, tubes, catheters. Gynaecological: Equipment, tubes, catheters, scopes, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products: Gloves, Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Intracutaneous Test	USP 43 (88)

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24	BIOLOGICAL-TOXICOLOGY	Urological devices: Catheters, stents. Cardiovascular devices: Catheters, Valves, stents, bags, electrodes, wires. Orthopaedic devices: Joints, blocks, implants, screws, pins, rods, tubes, coatings. Ocular devices: Intraocular lens, implements, eye drops, containers. Surgical implements: Surgical implements, sutures, mesh; staplers. Respiratory devices: Tubes, catheters. Gastrointestinal devices: Tubes, catheters, Paediatrics: Tubes, catheters. Neurological: Implements, needles, catheters. Gynaecological: Equipment, catheters, rings, loops. Haematological devices and IV sets: Filters, blood collections sets, bags, Intravenous sets, needles, syringes. Wound care products. Personal care products:Intrauterine devices, contraceptives, lubricants, incubators. Raw Ingredients: Collagen, plastics, metals, polymers. Dental products.	Bacterial Reverse Mutation (AMES) Test	ISO 10993-3