



INTERNATIONAL
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CERTIFICATE OF ACCREDITATION

This is to attest that

TUV SUD SOUTH ASIA PVT LTD, BENGALURU

PLOT NO.3-P1-B, HITECH DEFENCE AREA & AEROSPACE PARK INDUSTRIAL AREA, SINGANAHALLI
VILLAGE BK PALAYA
BENGALURU, KA, 562149, INDIA

Testing Laboratory TL-1253

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date May 22, 2024



International Accreditation Service
Issued under the authority of IAS management

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TUV SUD SOUTH ASIA PVT LTD, BENGALURU

Contact Name Rajarajeswari Vijayarangan

Contact Phone +91-9182901338

Accredited to ISO/IEC 17025:2017

Effective Date May 22, 2024

MEDICAL DEVICES OR ITS EXTRACTS (AS APPLICABLE)	
Urinary Catheters, Intravascular Catheters, Internal Drug Delivery Catheters and Ventricular Assist Devices, Bladder Catheters, Infusion Sets, Transfusion Sets, Atherectomy Devices, Intravascular Ultrasound Catheters, Antegrade/Retrograde Coronary Perfusion Catheters, Guide Wires, Cannula, Parenteral Nutrition Catheters, Central Venous & Catheters and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3 rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993- Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5 th edition 2021 (Sample preparation and reference materials)	Genotoxicity Test (Bacterial Reverse Mutation Test)
Blood Bags, and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample	Cytotoxicity Test (Elution method)

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preparation and reference materials)	
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021(Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021(Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993- Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Cardiovascular Devices (Pacemaker Electrodes, Pacemakers, Heart Valves, Vascular Grafts, Drug Eluting Bioresorbable Cardiac Stent System, Temporary Pacemaker Electrodes, Artificial Arteriovenous Fistulae, and Other Devices That Come In Direct Contact With Circulating Blood) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021(Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021(Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5;	Genotoxicity Tests (Bacterial Reverse Mutation Test)

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Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	
Dental (Dental Cement, Dental Filling Materials, Dental, Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Protective Equipment's (Mask, Gloves, Coverall, etc.), Disposables (Needles, Syringe) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)



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preparation and reference materials)	
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
External Communicating Devices (Dialysers, Dialysis Tubing and Accessories, Solution Administration Sets, Extension Sets, Transfer Sets and Blood Administration Sets, Drugs Supply Devices, Closed System IV Cannula) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Hypodermic Needles and Insulin Needles	

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ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Implant Devices (Skin Staples, Breast Implants, Sutures, Bioresorbable Bare Metal Cardiac Stent System, Subperiosteal Implants, Cochlear Implant, Artificial Larynxes, Stunts, Hernia Mesh, Replacement Tendons, Ligation Clips, Cardiovascular Devices and Orthopedic Implants) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample	Cytotoxicity (Colony formation cytotoxicity test)



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preparation and reference materials)	
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Male and Female Condoms and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Natural Orifice Devices (Intravaginal Devices, Condoms IUD and HIUD, Intra-Uterine Devices, Ligation Clips, Latex Oral Dam and Other Devices That Come In Contact With Natural Orifice) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample	Cytotoxicity Test (Elution method)

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preparation and reference materials)	
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Ophthalmic (Contact Lenses, Ophthalmic Solutions, Corneal Storage Media, Gels Other Devices That Come in Contact With Eye and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5;	Genotoxicity Tests (Bacterial Reverse Mutation Test)



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Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	
Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Probes/Electrodes (Electrodes, Probes of Monitors of Various Types Like ECG, Blood Pressure, Ultrasound, Neuromuscular Sensors and Simulators and Other Devices Which Come in Contact With Intact Skin) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)



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ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Respiratory Devices (Oxygenators, Extracorporeal Oxygenator Tubing and Accessories, Endotracheal Tubes and Other Devices That Come in Contact With the Airway Breathing Path) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015,	Genotoxicity Tests (Bacterial Reverse Mutation Test)



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Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	
Scopes (Laparoscopes, Arthroscopes, Draining System, Bronchoscopes, Laryngoscope) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Surgical Instruments (Scalpels, Haemostat)	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample	Cytotoxicity Test (MTT cytotoxicity test)



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preparation and reference materials)	
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Wound Care Devices (Fixation Tapes, Compression Bandages, Wound Dressing Materials, Dressings or Healing Devices, Occlusive Patches for Ulcers, Burns and Granulation Tissue Other Devices Which Come in Contact With Breached or Compromised Surface) and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021	Genotoxicity Tests (Bacterial Reverse Mutation Test)



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(Sample preparation and reference materials)	
Syringes With Needles, Tubular Rings, Copper-T, Intraocular Implants, Surgical Gloves, Vascular Devices and IV Sets, Coronary Stent, Orthopedic Devices, Joints, Screws, Plates, Bone Cements, Internal Prosthetic Replacements, Ablation Device, Scalp Vein Set, Surgical Dressings, Umbilical Tapes, Preservative Solution, Nebulizer, Blood Pressure Monitoring Device, Glucometer, Digital Thermometer, All Implantable Medical Device Equipment, Disinfectant and Insecticide Specified on Medical Device, Drug Eluting Stents, Eye Drops and Urological Devices, Gastrointestinal Devices, Paediatric Devices, Neurological Devices, Gynecological Devices, Hematological Devices, Surgical Implements, Ventilators, Raw Ingredients (Collagen, Chitosan, Polymers, Metals, Rubbers, Resins), Blood Gas Pathways and Other Medical Devices	
ISO 10993- Part 5: 3rd edition 2009, Section: 8.3; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (Elution method)
ISO 10993- Part 5: 3rd edition 2009, Annex C; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity Test (MTT cytotoxicity test)
ISO 10993- Part 5: 3rd edition 2009, Annex B; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Cytotoxicity (Colony formation cytotoxicity test)
ISO-10993- Part 3: 3rd edition 2014, Section: 5; Supplement ISO/TR 10993 – Part 33: 1st edition 2015, Section: 6; ISO 10993- Part 12: 5th edition 2021 (Sample preparation and reference materials)	Genotoxicity Tests (Bacterial Reverse Mutation Test)
Ablation Device, Cement Restrictor, I.V. Cannulae, 10 ul Regular Sterile Tips, 1000ul LR Sterile Tips, 10ul LR Sterile Tips, 15ul Sterile Centrifuge Tubes, 200 ul LR Sterile Tips, 25 Gauge 30 Gauge, 50 ml Sterile Centrifuge Tubes, Blow Extruded Single Blood Bag (Type A and Type B), Bone Cements, Bone Screw, Catheters, Cemented Femoral Stem, Coronary Stents, Cut380a, Disposable Hypodermic Syringes, Disposable Perfusion Set, Drug Eluting Stents, Heart Valves, Internal Prosthetic Replacements, Intra Ocular Implants, Intra Ocular Lenses, Joints, Nails, Nodular Head, Orthopedic Devices, Plates, Silicon Tubal Ring, Simple Plain Latex Type, Straight Single Use, Sutures, Uncemented Femoral Stem and Other Medical Devices	

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<p>USP Chapter 71:2024; ISO 11737- Part 2, 3rd edition: 2019</p>	<p>Sterility Test</p>
<p>Cement Restrictor, I.V. Cannulae, 10 ul Regular Sterile Tips, 1000ul LR Sterile Tips, 10ul LR Sterile Tips, 15ul Sterile Centrifuge Tubes, 200 ul LR Sterile Tips, 25 Gauge 30 Gauge, 50 ml Sterile Centrifuge Tubes, Ablation Device, Bone Cements, Bone Screw, Catheters, Cemented Femoral Stem, Coronary Stents, Disposable Hypodermic Syringes, Disposable Perfusion Set, Drug Eluting Stents, Heart Valves, Internal Prosthetic Replacements, Intra Ocular Implants, Intra Ocular Lenses, Joints, Nails, Nodular Head, Orthopedic Devices, Plates, Sutures, Uncemented Femoral Stem and Other Medical Devices</p>	
<p>USP Chapter 85:2024; ISO 11737- Part 3, 1st Edition:2023; USP Chapter 161:2024</p>	<p>Bacterial Endotoxin Test – (BET)</p>
<p>Finished Medical Devices/Pharmaceutical Containers Closer Devices/Packing Material and Components-Extractable and Leachable Screening – Inorganic and Organic Compounds</p>	
<p>ISO 10993-1: 2018; ISO 10993-12: 2021; ISO 10993-18:2020; USP Chapter 1663 :2024</p>	<p>Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems Biological evaluation of medical devices- Part 1: Evaluation and Testing within a risk management process Biological evaluation of medical devices - Part 12: Sample preparation and reference materials Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor</p> <p>Antimony (Sb), Aluminum (Al), Arsenic (As), Barium (Ba), Cadmium (Cd), Chromium (Cr), Cobalt (Co), Copper (Cu), Europium (Eu), Gadolinium (Gd), Gold (Au), Iridium (Ir), Lead (Pb), Lanthanum (La), Lithium (Li), Mercury (Hg), Molybdenum (Mo), Niobium (Nb), Nickel (Ni), Osmium (Os), Platinum (Pt), Rhodium (Rh), Ruthenium (Ru), Selenium (Se), Strontium (Sr), Silver (Ag), Tantalum (Ta),Thallium (Tl), Terbium (Tb), Tungsten (W), Titanium (Ti), Tin (Sn), Vanadium (V) Yttrium (Y), Zirconium(Zr)</p>
<p>ISO 10993-1: 2018; ISO 10993-12: 2021; ISO 10993-18:2020; USP Chapter 1663 :2024</p>	<p>Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems Biological evaluation of medical devices- Part 1: Evaluation and Testing within a risk management process Biological evaluation of medical devices - Part 12: Sample preparation and reference materials Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor</p> <p>Dipentyl phthalates; Bis-methoxy ethyl phthalates, Di iso butyl phthalates; 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters; 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; Di-n</p>



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<p>ISO 10993-1: 2018; ISO 10993-12: 2021; ISO 10993-18:2020; USP Chapter 1663 :2024 (cont'd.)</p>	<p>hexylphthalate; Dimethyl phthalate; Di Decyl Phtalates (DDP); Di-n-propyl phthalate (DPPrP); Diisooctyl phthalate (DIOP); Di-2-propyl heptyl phthalate (DPHP); DiisoHexylphthalate (DIHxP); 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear; 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl; diesters with 8 0.3% of dihexyl phthalate (EC No. 201-559-5); 1,2-Benzenedicarboxylic acid dipentylester; branched and linear (CAS# 84777-06-0); N-nitrosodimethylamine (NDMA); N-nitrosodiethylamine (NDEA); N-nitrosodipropylamine (NDPA); N-nitrosodibutylamine (NDBA); N-nitrosopiperidine (NPIP); N-nitrosopyrrolidine (NPYR); N-nitrosomorpholine (NMOR); N-nitrosodibenzylamine (NDBZA); N-nitrosodiisononylamine (NDINA); N-nitroso N-methyl-N-phenylamine (NMPPhA); N-nitroso N-ethyl N-phenylamine (NEPhA); N-nitrosodiethanolamine(NDELA); N-nitrosodiisopropylamine(NDiPA); N-nitrosobutylamine(NDiBA); Acetone; DCM; n-Hexane; Chloroform; THF; Cyclohexane; CCl4; Benzene; Trichloroethylene; 1,1,2-Trichloro Ethane; Toluene; Tetrachloroethylene; Xylene; N, N-Dimethylacetamide; Cyclohexanone; Styrene; 1,2,3-trichloro Propane; Pentachloro Ethane; 2-methoxy-Ethanol; 1,2-dimethoxyEthane; 2-ethoxy-Ethanol; 2-Methoxyethyl acetate; Ethylbenzene; 2-Ethoxyethyl acetate; 1,1,2,2-tetrachloro-Ethane; Phenol; 3-methyl-Phenol; trans-Di-1,2-Chloroethylene; cis-Dichloroethylene; 1,2-Dichloroethane; 1,1,1-Trichloroethane; 1,1,1,2-Tetrachloroethane; Trimethylol propane; Dibromochloromethane; Bromochloromethane; 1,1,2-Trichloroethane; Hexachlorobutadiene; Butylated hydroxy anisole; Butylated hydroxy toluene; Diphenylamine; Erucamide; Irgafos 168; Irganox 1076; Irganox 1010; Irganox 3114; Irganox 1330; Irganox PS 800; Tinuvin P; Antioxidant 2246; Oleamide; 2-(2H-Benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl) phenol – UV 350; 2-(2H-Benzotriazol-2-yl)-4,6-di-tert-pentylphenol – UV 328; 2,4-Di-tert-butyl-6-(5-chlorobenzotriazol-2-yl) phenol – UV 327; 2-Benzotriazol-2-yl-4,6-di-tert-butylphenol – UV 320; Bisphenol A (BPA); Bisphenol S (BPS); Bisphenol F (BPF); Bisphenol AF (BPAF); Bisphenol Z; Bisphenol B; Perfluorobutane-1-sulfonic acid (PFBS) Perfluoro-n-hexanoic acid (PFHxA) Perfluorohexane-1-sulfonic acid (PFHxS) Perfluoro-n-octanoic acid (PFOA) Perfluoro-n-nonanoic acid (PFNA), Perfluorooctane-1-sulfonic acid (PFOS) Perfluoro-n-decanoic acid (PFDA) Perfluoro-n-undecanoic acid (PFUnDA) Perfluoro-n-dodecanoic acid (PFDoDA) Perfluoro-n-tridecanoic acid (PFTrDA) Perfluoro-n-tetradecanoic acid (PFTeDA) Perfluoro-n-butanoic acid (PFBA) Perfluoro-n-pentanoic acid (PFPeA) Tetrabutylphosphonium 2H,2H-Perfluorodecanoate (H2PFDA) 2H,2H,3H,3H-Perfluoroundecanoic acid (4HPFUnA); 7H-Dodecafluoroheptanoic acid (7HPFHpA); Perfluoro-n-heptanoic acid (PFHpA) Perfluoroheptanesulfonic acid (PFHpS) Perfluoro (3,7-dimethyloctanoic acid) [PF-3,7-DMOA]; Perfluorooctane sulfonamide (PFOSA) N-Methylperfluoro-1-octanesulfonamide (N-Me-FOSA); N-Ethylperfluoro-1-octanesulfonamide (N-ET-FOSA); Perfluoro-1-decanesulfonate (PFDS) 1H,1H,2H,2H-Perfluorohexanesulfonic acid (4:2 FTS); 1H,1H,2H,2H-Perfluorooctanesulfonic acid (6:2 FTS); 1H,1H,2H,2H-Perfluorodecanesulfonic acid (8:2 FTS); 1H,1H,2H,2H-Perfluorododecanesulfonic acid (10:2 FTS); N-Methylperfluorooctanesulfonamidoethanol (N-Me-FOSE);</p>
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SCOPE OF ACCREDITATION

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	N-Ethyl-N-(2-hydroxyethyl) perfluorooctanesulfonamide [N-Et-FOSE]
TYVEK POUCHES Aluminum Pouches, Blister Packaging, Polymer Packaging, Paper Packaging and Other Packaging Materials	
ASTM F1886/F1886M – 16	Visual Inspection Test
ASTM F1929-23 (Section 11, Method A: Injection Method)	Dye Penetration Test
ASTM F1140/F1140M – 13 (Reapproved 2020) (Section 9.1 & 9.1.1 Test Method A (Burst Test, Open Package Test))	Burst Test
ASTM F2338 – 09 (Reapproved 2020)	Vacuum Leak Test
ASTM F88/F88M – 23	Seal Strength Test
ISO 5636-5 3rd Edition: 2013	Air Permeability Test (Gurley Method)
ASTM F2029 – 16 (Reapproved 2021)	Heat Seal Test
ASTM D3078 – 02 (Reapproved 2021)	Bubble emission test

Note:

MTT: 3- (4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide

ASTM: American Society for Testing and Materials

ISO: International Organization for Standardization

USP: United States Pharmacopoeia

