National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 1 of 27

Validity 07/04/2022 to 06/04/2024 **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 Facility				
1	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Acute Systemic Toxicity Test	ISO 10993-11
2	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Acute Systemic Toxicity Test	ISO 10993-12
3	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU cytotoxicity, MTT Cytotoxicity	ISO 10993-12
4	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU cytotoxicity, MTT Cytotoxicity	ISO 10993-5
5	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Genotoxicity Tests; Bacterial Reverse Mutation Test In vitro and In vivo Mammalian Chromosomal Aberration Test In vitro and In vivo Mammalian Micronucleus Test Mouse Lymphoma Gene Assay	ISO 10993-12
6	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Genotoxicity Tests; Bacterial Reverse Mutation Test In vitro and In vivo Mammalian Chromosomal Aberration Test In vitro and In vivo Mammalian Micronucleus Test Mouse Lymphoma Gene Assay	ISO-10993-3

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 2 of 27

Validity 07/04/2022 to 06/04/2024 **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
7	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
8	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Hemocompatibility Tests	ISO 10993-12
9	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Hemocompatibility Tests	ISO 10993-4
10	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Material Mediated Pyrogenicity in Rabbits	ISO 10993-12
11	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Material Mediated Pyrogenicity in rabbits	ISO-10993-11
12	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Skin Sensitization Test	ISO 10993-10

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 3 of 27

Validity 07/04/2022 to 06/04/2024 **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
13	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Skin Sensitization Test	ISO 10993-12
14	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Test of Irritation	ISO 10993-12
15	BIOLOGICAL-TOXICOLOGY	(Urinary catheters, Intravascular catheters, Internal drug-delivery catheters and ventricular assist devices, Bladder Catheter, infusion sets, transfusion sets, atherectomy devices, Intravascular ultrasound catheters, antegrade/retrograde coronary perfusion catheters, guide wires, cannulae, parenteral nutrition catheters, central venous, catheters	Test of Irritation	ISO 10993-23
16	BIOLOGICAL-TOXICOLOGY	Blood Bags	Acute Systemic Toxicity Test	ISO 10993-11
17	BIOLOGICAL-TOXICOLOGY	Blood Bags	Acute Systemic Toxicity Test	ISO 10993-12
18	BIOLOGICAL-TOXICOLOGY	Blood Bags	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU cytotoxicity, MTT Cytotoxicity	ISO 10993-12
19	BIOLOGICAL-TOXICOLOGY	Blood Bags	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU cytotoxicity, MTT CytotoxicityCytotoxicity	ISO 10993-5
20	BIOLOGICAL-TOXICOLOGY	Blood Bags	Genotoxicity Tests; Bacterial Reverese Mutation Test In vitro and In vivo Mammalian Chromosomal Aberration Test In vitro and In vivo Mammalian Micronucleus Test Mouse Lymphoma Gene Assay	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 4 of 27

Validity 07/04/2022 to 06/04/2024 **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
21	BIOLOGICAL-TOXICOLOGY	Blood Bags	Genotoxicity Tests; Bacterial Reverese Mutation Test In vitro and In vivo Mammalian Chromosomal Aberration Test In vitro and In vivo Mammalian Micronucleus Test Mouse Lymphoma Gene Assay	ISO-10993-3
22	BIOLOGICAL-TOXICOLOGY	Blood Bags	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
23	BIOLOGICAL-TOXICOLOGY	Blood Bags	Hemocompatibility Tests	ISO 10993-12
24	BIOLOGICAL-TOXICOLOGY	Blood Bags	Hemocompatibility Tests	ISO 10993-4
25	BIOLOGICAL-TOXICOLOGY	Blood Bags	Material Mediated Pyrogenicity in Rabbits	ISO 10993-12
26	BIOLOGICAL-TOXICOLOGY	Blood Bags	Material Mediated Pyrogenicity In rabbits	ISO-10993-11
27	BIOLOGICAL-TOXICOLOGY	Blood bags	Skin Sensitization Test	ISO 10993-10
28	BIOLOGICAL-TOXICOLOGY	Blood Bags	Skin Sensitization Test	ISO 10993-12
29	BIOLOGICAL-TOXICOLOGY	Blood bags	Test of Irritation	ISO 10993-23
30	BIOLOGICAL-TOXICOLOGY	Blood Bags	Test of Irritation	ISO-10993-12
31	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Acute Systemic Toxicity Test	ISO 10993-11
32	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Acute Systemic Toxicity Test	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 5 of 27

Validity 07/04/2022 to 06/04/2024 **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
33	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
34	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
35	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
36	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
37	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
38	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Hemocompatibility Tests	ISO 10993-12
39	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Hemocompatibility Tests	ISO 10993-4

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 6 of 27

Validity 07/04/2022 to 06/04/2024 **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
40	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Material Mediated Pyrogenicity in Rabbits	ISO 10993-12
41	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Material Mediated Pyrogenicity in Rabbits	ISO-10993-11
42	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Skin Sensitization Test	ISO 10993-10
43	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Skin Sensitization Test	ISO 10993-12
44	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Test of Irritation	ISO 10993-12
45	BIOLOGICAL-TOXICOLOGY	Cardiovascular devices (Pacemaker electrodes, Pacemakers, Heart valves, vascular grafts, Drug Eluting Bioresorbable cardiac stent system, Temporary pacemaker electrodes, Artificial arteriovenous fistulae and other devices which comes in direct contact with circulating blood)	Test of Irritation	ISO 10993-23
46	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Acute Systemic Toxicity Test	ISO 10993-11
47	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Acute Systemic Toxicity Test	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 7 of 27

Validity 07/04/2022 to 06/04/2024 **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
48	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
49	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
50	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
51	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
52	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
53	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Hemocompatibility Tests	ISO 10993-12
54	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Hemocompatibility Tests	ISO 10993-4
55	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Material Mediated Pyrogenicity in rabbits	ISO 10993-12
56	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Material Mediated Pyrogenicity in rabbits	ISO-10993-11
57	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Skin Sensitization Test	ISO 10993-10

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 8 of 27

Validity 07/04/2022 to 06/04/2024 **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
58	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Skin Sensitization Test	ISO 10993-12
59	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Test of Irritation	ISO 10993-12
60	BIOLOGICAL-TOXICOLOGY	Dental (Dental Cements, Dental Filling Materials, Dental Prostheses, Orthodontic Devices, Permanent Crowns, Dental Abutment)	Test of Irritation	ISO 10993-23
61	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Acute Systemic Toxicity Test	ISO 10993-11
62	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Acute Systemic Toxicity Test	ISO 10993-12
63	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
64	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
65	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
66	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
67	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
68	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Hemocompatibility Tests	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 9 of 27

Validity 07/04/2022 to 06/04/2024 **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
69	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Hemocompatibility Tests	ISO 10993-4
70	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Material Mediated Pyrogenicity in Rabbits	ISO 10993-12
71	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Material Mediated Pyrogenicity in Rabbits	ISO-10993-11
72	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Skin Sensitization Test	ISO 10993-10
73	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Skin Sensitization Test	ISO 10993-12
74	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Test of Irritation	ISO 10993-12
75	BIOLOGICAL-TOXICOLOGY	Disposables (Needles, Gloves, PPE, Marks, Syringe)	Test of Irritation	ISO 10993-23
76	BIOLOGICAL-TOXICOLOGY	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)	Acute Systemic Toxicity Test	ISO 10993-11
77	BIOLOGICAL-TOXICOLOGY	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)	Acute Systemic Toxicity Test	ISO 10993-12
78	BIOLOGICAL-TOXICOLOGY	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)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
79	BIOLOGICAL-TOXICOLOGY	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)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
80	BIOLOGICAL-TOXICOLOGY	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)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 10 of 27

Validity 07/04/2022 to 06/04/2024 **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
81	BIOLOGICAL-TOXICOLOGY	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)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
82	BIOLOGICAL-TOXICOLOGY	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)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
83	BIOLOGICAL-TOXICOLOGY	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)	Hemocompatibility Tests	ISO 10993-12
84	BIOLOGICAL-TOXICOLOGY	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)	Hemocompatibility Tests	ISO 10993-4
85	BIOLOGICAL-TOXICOLOGY	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)	Material Mediated Pyrogenicity in Rabbits	ISO 10993-12
86	BIOLOGICAL-TOXICOLOGY	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)	Material Mediated Pyrogenicity in Rabbits	ISO-10993-11
87	BIOLOGICAL-TOXICOLOGY	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)	Skin Sensitization Test	ISO 10993-10
88	BIOLOGICAL-TOXICOLOGY	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)	Skin Sensitization Test	ISO 10993-12
89	BIOLOGICAL-TOXICOLOGY	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)	Test of Irritation	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 11 of 27

Validity 07/04/2022 to 06/04/2024 **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
90	BIOLOGICAL-TOXICOLOGY	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)	Test of Irritation	ISO 10993-23
91	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Acute Systemic Toxicity Test	ISO 10993-11
92	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Acute Systemic Toxicity Test	ISO 10993-12
93	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
94	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
95	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
96	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
97	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
98	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Hemocompatibility Tests	ISO 10993-12
99	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Hemocompatibility Tests	ISO 10993-4
100	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Material Mediated Pyrogenicity In rabbits	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 12 of 27

Validity 07/04/2022 to 06/04/2024 **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
101	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Material Mediated Pyrogenicity In rabbits	ISO-10993-11
102	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Skin Sensitization Test	ISO 10993-10
103	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Skin Sensitization Test	ISO 10993-12
104	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Test of Irritation	ISO 10993-23
105	BIOLOGICAL-TOXICOLOGY	Hypodermic needles and Insulin needles	Test of Irritation	ISO 10993-12
106	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Acute Systemic Toxicity Test	ISO 10993-11
107	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Acute Systemic Toxicity Test	ISO 10993-12
108	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
109	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
110	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12:

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 13 of 27

Validity 07/04/2022 to 06/04/2024 **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
111	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
112	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
113	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Hemocompatibility Tests	ISO 10993-12
114	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Hemocompatibility Tests	ISO 10993-4
115	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Material Mediated Pyrogenicity in Rabbits	ISO 10993-12
116	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Material Mediated Pyrogenicity in Rabbits	ISO-10993-11
117	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Skin Sensitization Test	ISO 10993-10

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 14 of 27

Validity 07/04/2022 to 06/04/2024 **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
118	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Skin Sensitization Test	ISO 10993-12
119	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Test of Irritation	ISO 10993-23
120	BIOLOGICAL-TOXICOLOGY	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 Orthopaedic implants)	Test of Irritation	ISO 10993-12
121	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Material Mediated Pyrogenicity In rabbits	ISO 10993-12
122	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Acute Systemic Toxicity Test	ISO 10993-11
123	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Acute Systemic Toxicity Test	ISO 10993-12
124	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU cytotoxicity, MTT Cytotoxicity	ISO 10993-12
125	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
126	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test , In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 15 of 27

Validity 07/04/2022 to 06/04/2024 **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
127	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test , Mouse Lymphoma Gene Assay	ISO 10993-33
128	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus, Test Mouse Lymphoma Gene Assay	ISO 10993-12
129	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Hemocompatibility Tests	ISO 10993-12
130	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Hemocompatibility Tests	ISO 10993-4
131	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Material Mediated Pyrogenicity In rabbits	ISO-10993-11
132	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Skin Sensitization Test	ISO 10993-10
133	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Skin Sensitization Test	ISO 10993-12
134	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Test of Irritation	ISO 10993-12
135	BIOLOGICAL-TOXICOLOGY	Male and Female condoms	Test of Irritation	ISO 10993-23
136	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Acute Systemic Toxicity Test	IISO 10993-11
137	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Acute Systemic Toxicity Test	ISO 10993-12
138	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 16 of 27

Validity 07/04/2022 to 06/04/2024 **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
139	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
140	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
141	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
142	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
143	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Hemocompatibility Tests	ISO 10993-12
144	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Hemocompatibility Tests	ISO 10993-4
145	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Material Mediated Pyrogenicity in rabbits	ISO 10993-12
146	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Material Mediated Pyrogenicity in rabbits	ISO-10993-11
147	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Skin Sensitization Test	ISO 10993-10

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 17 of 27

Validity 07/04/2022 to 06/04/2024 **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
148	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Skin Sensitization Test	ISO 10993-12
149	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Test of Irritation	ISO 10993-12
150	BIOLOGICAL-TOXICOLOGY	Natural Orifice devices (Intravaginal devices, Condoms IUD and HIUD, intra-uterine devices, Ligation clips, Latex Oral Dam and other devices which comes in contact with natural orifice)	Test of Irritation	ISO 10993-23
151	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Acute Systemic Toxicity Test	ISO 10993-12
152	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Acute Systemic Toxicity Test	ISO 10993-11
153	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
154	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
155	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
156	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 18 of 27

Validity 07/04/2022 to 06/04/2024 **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
157	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
158	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Hemocompatibility Tests	ISO 10993-12
159	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Hemocompatibility Tests	ISO 10993-4
160	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Material Mediated Pyrogenicity in rabbits	ISO 10993-12
161	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Material Mediated Pyrogenicity in rabbits	ISO-10993-11
162	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Skin Sensitization Test	ISO 10993-10
163	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Skin Sensitization Test	ISO 10993-12
164	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Test of Irritation	ISO 10993-12
165	BIOLOGICAL-TOXICOLOGY	Ophthalmic (Contact lenses, Ophthalmic solutions, Corneal Storage Media, Gels other devices which comes in contact with eye)	Test of Irritation	ISO 10993-23
166	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Acute Systemic Toxicity Test	ISO 10993-12
167	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Acute Systemic Toxicity Test	ISO 10993-11
168	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 19 of 27

Validity 07/04/2022 to 06/04/2024 **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
169	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Cytotoxicity Test;Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
170	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
171	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
172	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
173	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Hemocompatibility Tests	ISO 10993-12
174	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Hemocompatibility Tests	ISO 10993-4
175	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Material Mediated Pyrogenicity in Rabbits	ISO 10993-12
176	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Material Mediated Pyrogenicity in Rabbits	ISO-10993-11
177	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Skin Sensitization Test	ISO 10993-10
178	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Skin Sensitization Test	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 20 of 27

Validity 07/04/2022 to 06/04/2024 **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
179	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Test of Irritation	ISO 10993-23
180	BIOLOGICAL-TOXICOLOGY	Orthopaedic Devices (Orthopaedic Pins, Plates, Replacement Joints, Bone Prostheses, Bone Cements, Bone Graft, External Prostheses)	Test of Irritation	ISO 10993-12
181	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Acute Systemic Toxicity Test	ISO 10993-11
182	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Acute Systemic Toxicity Test	ISO 10993-12
183	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
184	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
185	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
186	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
187	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 21 of 27

Validity 07/04/2022 to 06/04/2024 **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
188	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Hemocompatibility Tests	ISO 10993-12
189	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Hemocompatibility Tests	ISO 10993-4
190	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Material Mediated Pyrogenicity in rabbits	ISO 10993-12
191	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Material Mediated Pyrogenicity in rabbits	ISO-10993-11
192	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Skin Sensitization Test	ISO 10993-10
193	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Skin Sensitization Test	ISO 10993-12
194	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Test of Irritation	ISO 10993-12
195	BIOLOGICAL-TOXICOLOGY	Probes/electrodes (Electrodes, Probes of monitors of various types like ECG, blood pressure, ultrasound, Neuromuscular sensors and simulators and other devices which comes in contact with intact skin)	Test of Irritation	ISO 10993-23
196	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Acute Systemic Toxicity Test	ISO 10993-11
197	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Acute Systemic Toxicity Test	ISO 10993-12
198	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 22 of 27

Validity 07/04/2022 to 06/04/2024 **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
199	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
200	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
201	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
202	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration, Test In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
203	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Hemocompatibility Tests	ISO 10993-12
204	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Hemocompatibility Tests	ISO 10993-4
205	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Material Mediated Pyrogenicity in Rabbits	ISO 10993-12
206	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Material Mediated Pyrogenicity in Rabbits	ISO-10993-11
207	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Skin Sensitization Test	ISO 10993-10

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 23 of 27

Validity 07/04/2022 to 06/04/2024 **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
208	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Skin Sensitization Test	ISO 10993-12
209	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Test of Irritation	ISO 10993-23
210	BIOLOGICAL-TOXICOLOGY	Respiratory devices (Oxygenators, Extracorporal oxygenator tubing and accessories, Endotracheal tubes and other devices which comes in contact with airway breathing path)	Test of Irritation	ISO 10993-12
211	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Acute Systemic Toxicity Test	ISO 10993-11
212	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Acute Systemic Toxicity Test	ISO 10993-12
213	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
214	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
215	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
216	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 24 of 27

Validity 07/04/2022 to 06/04/2024 **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
217	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
218	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Hemocompatibility Tests	ISO 10993-12
219	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Hemocompatibility Tests	ISO 10993-4
220	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Material Mediated Pyrogenicity in rabbits	ISO 10993-12
221	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Material Mediated Pyrogenicity in rabbits	ISO-10993-11
222	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Skin Sensitization Test	ISO 10993-10
223	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Skin Sensitization Test	ISO 10993-12
224	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Test of Irritation	ISO 10993-12
225	BIOLOGICAL-TOXICOLOGY	Scopes (Laparoscopes, Arthroscopes, draining System, Bronchoscopes, Laryngoscope)	Test of Irritation	ISO 10993-23
226	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Haemostat)	Hemocompatibility Tests	ISO 10993-12
227	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Haemostat)	Material Mediated Pyrogenicity In rabbits	ISO 10993-12
228	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Haemostat)	Skin Sensitization Test	ISO 10993-12
229	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Haemostat)	Test of Irritation	ISO 10993-12
230	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Acute Systemic Toxicity Test	ISO 10993-11
231	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Acute Systemic Toxicity Test	ISO 10993-12
232	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 25 of 27

Validity 07/04/2022 to 06/04/2024 **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
233	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5:
234	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
235	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
236	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
237	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Hemocompatibility Tests	ISO 10993-4
238	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Material Mediated Pyrogenicity In rabbits	ISO-10993-11
239	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Skin Sensitization Test	ISO 10993-10
240	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Skin Sensitization Test	ISO 10993-10
241	BIOLOGICAL-TOXICOLOGY	Surgical Instruments (Scalpels, Hemostat)	Test of Irritation	ISO 10993-23
242	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Acute Systemic Toxicity Test	ISO 10993-11

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 26 of 27

Validity 07/04/2022 to 06/04/2024 **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
243	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Acute Systemic Toxicity Test	ISO 10993-12
244	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-12
245	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Cytotoxicity Test; Elution Method, Agar Overlay Assay, Direct Contact Assay, NRU Cytotoxicity, MTT Cytotoxicity	ISO 10993-5
246	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-12
247	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO 10993-33
248	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Genotoxicity Tests; Bacterial Reverse Mutation Test, In vitro and In vivo Mammalian Chromosomal Aberration Test, In vitro and In vivo Mammalian Micronucleus Test, Mouse Lymphoma Gene Assay	ISO-10993-3
249	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Hemocompatibility Tests	ISO 10993-12
250	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Hemocompatibility Tests	ISO 10993-4

SCOPE OF ACCREDITATION

Laboratory Name : BIONEEDS INDIA PRIVATE LIMITED, DEVARAHOSAHALLY, SOMPURA HOBLI, NELAMANGALA TALUK, BENGALURU, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-6647 **Page No** 27 of 27

Validity 07/04/2022 to 06/04/2024 **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
251	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Material Mediated Pyrogenicity in rabbits	ISO 10993-12
252	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Material Mediated Pyrogenicity in rabbits	ISO-10993-11
253	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Skin Sensitization Test	ISO 10993-10
254	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Skin Sensitization Test	ISO 10993-12
255	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Test of Irritation	ISO 10993-12
256	BIOLOGICAL-TOXICOLOGY	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 comes in contact with breached or compromised surface)	Test of Irritation	ISO 10993-23