BUREAU OF INDIAN STANDARDS

Program of Work

MHD 19 : In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices

Scope: To formulate Indian Standards on: a) In-vitro Diagnostic kits, reagents, analyzers and associated software b) Biological and clinical evaluation of medical and dental materials, devices, implants together with standardization of biological test methods applicable to those materials and devices, and c) Good clinical practice principles to clinical investigations in humans of those devices

Liaison: **ISO TC-194 (P):** *Biological and clinical evaluation of medical devices*

Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS/ISO 10993-2 : 2006 ISO 10993-2:2006 ISO 10993-2:2006	Biological Evaluation of Medical Devices Part 2 Animal Welfare Requirements (First Revision)		-	Identical under single numbering
2	IS/ISO 10993-3 : 2014 ISO 10993-3 : 2014 ISO 10993-3 : 2014	Biological evaluation of medical devices Part 3 Tests for Genotoxicity, Carcinogenicity and Reproductive toxicity (First Revision)		-	Identical under single numbering
3	IS/ISO 10993-4 : 2017 ISO 10993-4 : 2017 ISO 10993-4 : 2017	Biological evaluation of medical devices Part 4 Selection of tests for interactions with blood		-	Identical under single numbering
4	IS/ISO 10993-5 : 2009 ISO 10993-5 : 2009 ISO 10993-5 : 2009	Biological evaluation of medical devices Part 5 Tests for in vitro cytotoxicity		-	Identical under single numbering
5	IS/ISO 10993-6 : 2016 ISO 10993-6 : 2016 ISO 10993-6 : 2016	Biological evaluation of medical devices Part 6 Tests for local effects after implantation		-	Identical under single numbering
6	IS/ISO 10993-7 : 2018 ISO 10993-7 : 2008 ISO 10993-7:2008	Biological evaluation of medical devices Part 7 Ethylene oxide sterilization residuals		-	Identical under single numbering
7	IS/ISO 10993-11 : 2017 ISO 10993-11 : 2017 ISO 10993-11 : 2017	Biological evaluation of medical devices Part 11 Tests for systemic toxicity		-	Identical under single numbering
8	IS/ISO 10993-12 : 2021 10993: Part 12 ISO 10993-12:2021	Biological Evaluation of Medical Devices Part 12 Sample Preparation and Reference Materials		-	Identical under single numbering

9	IS/ISO 10993-13 : 2010 ISO 10993-13:2010 ISO 10993-13:2010	Biological evaluation of medical devices Part 13 Identification and quantification of degradation products from polymeric medical devices		-	Identical under single numbering
10	IS/ISO 10993-14 : 2001 ISO 10993-14:2001 ISO 10993-14:2001	Biological evaluation of medical devices Part 14 Identification and quantification of degradation products from ceramics		-	Identical under single numbering
11	IS/ISO 10993-16 : 2017 ISO 10993-16 : 2017 ISO 10993-16 : 2017	Biological Evaluation of Medical Devices Part 16 Toxicokinetic Study Design for Degradation Products and Leachables		-	Identical under single numbering
12	IS/ISO 10993-17 : 2002 ISO 10993-17 : 2002 ISO 10993-17 : 2002	Biological Evaluation of Medical Devices Part 17 Establishment of Allowable Limits for Leachable Substances		-	Identical under single numbering
13	IS/ISO 10993-18 : 2020 10993: Part 18 ISO 10993-18:2020	Biological evaluation of medical devices Part 18 Chemical characterization of medical device materials within a risk management process		-	Identical under single numbering
14	IS/ISO/TS 10993-20 : 2006 ISO/TS 10993-20:2006 ISO/TS 10993-20:2006	Biological evaluation of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices		-	Identical under single numbering
15	IS/ISO/TR 10993-22 : 2017 ISO/TR 10993-22 : 2017 ISO/TR 10993-22:2017	Biological Evaluation of Medical Devices Part 22 Guidance on Nanomaterials		-	Identical under single numbering
16	IS/ISO 13022 : 2012 ISO 13022 : 2012 ISO 13022:2012	Medical products containing viable human cells - Application of risk management and requirements for processing practices		-	Identical under single numbering
17	IS/ISO 14155 : 2020 ISO 14155: 2020 ISO 14155: 2020	Clinical investigation of medical devices for human subjects - Good clinical practice		-	Identical under single numbering
18	IS/ISO 15197 : 2013 ISO 15197 : 2013 Reviewed In : 2020 ISO 15197 : 2013	In vitro Diagnostic Test Systems - Requirements for Blood-Glucose Monitoring System for Self-Testing in Managing Diabetes Mellitus (First Revision)	January, 2020	-	Identical under single numbering
19	IS/ISO 15198 : 2004 ISO 15198 : 2004 ISO 15198:2004	Clinical Laboratory Medicine - In vitro Diagnostic Medical Devices - Validation of User Quality Control Procedures by the Manufacturer		-	Identical under single numbering
20	IS/ISO/TR 15499 : 2016 ISO/TR 15499 : 2016 ISO/TR 15499 : 2016	Biological evaluation of medical devices - Guidance on the conduct of biological evaluation within a risk management process		-	Identical under single numbering
21	IS/ISO 17511 : 2020	In Vitro Diagnostic Medical		-	Identical under single

	ISO 17511 : 2020 ISO 17511:2020	Devices - Requirements for Establishing Metrological Traceability of Values Assigned to Calibrators, Trueness Control Materials and Human Samples			numbering
22	IS 17713 : 2023	In-Vitro Diagnostic Devices - ELISA Plate Reader		-	Indigenous
23	IS 17714 : 2023	In-Vitro Diagnostic Devices - Automated ELISA Processor		-	Indigenous
24	IS 17715 : 2023	In-vitro Diagnostic Device - ELISA Plate Washer		-	Indigenous
25	IS 17717 (Part 1) : 2023	In-Vitro Diagnostic Device - Automated Clinical chemistry Analyzer - Part 1 Wet Chemistry Analyzer		-	Indigenous
26	IS 17717 (Part 2) : 2023	In-Vitro Diagnostic (IVD) Device - Automated Clinical Chemistry Analyzer Part 2 Dry Chemistry Analyzer		-	Indigenous
27	IS 17718 : 2022	Performance testing of In-vitro Diagnostics IVD Reagent Kit alpha - Amylase CNP-G3 Liquid Stable Clinical Chemistry Reagents/ Kits		-	Indigenous
28	IS 17719 : 2023	In-Vitro Diagnostic (IVD) Medical Device - Automatic Slide Staining Instrument		-	Indigenous
29	IS 17720 : 2023	In-vitro Diagnostic Device - Automated Blood Culture and Microbial Detection System		-	Indigenous
30	IS 17721 : 2024	In-vitro Diagnostic (IVD) Devices - Electrolyte Analyzer		-	Indigenous
31	IS 17724 (Part 1) : 2023 IEC 61010-1: 2010 + AMD1:2016 + COR1:2019	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1 General Requirements (IEC 61010-1: 2010 + AMD1:2016 + COR1:2019, MOD)		-	Modified/Technically Equivalent
32	IS 17724 (Part 2) : 2023 IEC 61010-2-051: 2018 IEC 61010-2-051: 2018	Safety Requirements for Electrical Equipment for Measurement, Control, And Laboratory Use Part 2 Particular Requirements for Laboratory Equipment used in Mixing and Stirring		-	Identical under dual numbering
33	IS 17724 (Part 3) : 2024 IEC 61010-2-081: 2019	Safety Requirements for Electrical Equipment for Measurement, Control, And Laboratory Use Part 3 Particular Requirements of Automatic and Semi-Automatic Laboratory Equipment used for Analysis and Other Purposes		-	Modified/Technically Equivalent
34	IS 17724 (Part 4) : 2023 IEC 61010-2-101: 2018	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 4 Particular Requirements for In-Vitro Diagnostic (IVD) Medical Equipment (IEC 61010-2-101 : 2018, MOD)		-	Modified/Technically Equivalent
35	IS 17784 (Part 1) : 2023	Electrical Equipment for Measurement, Control and		-	Modified/Technically Equivalent

	IEC 61326-1: 2020	Laboratory Use - EMC Requirements Part 1 General Requirements (IEC 61326-1: 2020, MOD)			
36	IS 17784 (Part 2) : 2023 IEC 61326-2-6: 2020	Electrical equipment for measurement, control and laboratory use - EMC requirements Part 2 Particular requirements for In-vitro diagnostic (IVD) medical equipment (IEC 61326-2-6 : 2020, MOD)		-	Modified/Technically Equivalent
37	IS 17932 (Part 1) : 2023 ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process (ISO 10993-1 : 2018, MOD)		-	Modified/Technically Equivalent
38	IS 17932 (Part 2) : 2024 ISO 10993-9: 2019	Biological Evaluation of Medical Devices Part 2 Framework for identification and quantification of potential degradation products		-	Modified/Technically Equivalent
39	IS 17932 (Part 3) : 2024 ISO 10993-15: 2019	Biological Evaluation of Medical Devices Part 3 Identification and quantification of degradation products from metals and alloys		-	Modified/Technically Equivalent
40	IS 17932 (Part 4) : 2024 ISO 10993-19: 2020	Biological Evaluation of Medical Devices Part 4 Physico-chemical morphological and topographical characterization of materials		-	Modified/Technically Equivalent
41	IS 17932 (Part 5) : 2024 ISO 10993-7:2019	Biological Evaluation of Medical Devices Part 5 Ethylene oxide sterilization residuals		-	Modified/Technically Equivalent
42	IS 17932 (Part 6) : 2023 ISO 10993-10: 2021	Biological Evaluation of Medical Devices Part 6 Tests for skin sensitization (ISO 10993-10 : 2021, MOD)		-	Modified/Technically Equivalent
43	IS 17932 (Part 7) : 2024 ISO 10993-23:2021	Biological Evaluation of Medical Devices Part 7 Tests for irritation ISO 10993-23:2021 MOD		-	Modified/Technically Equivalent
44	IS/ISO 22442-1 : 2015 ISO 22442-1 : 2015 ISO 22442-1 : 2015	Medical Devices Utilizing Animal Tissues and their Derivatives Part 1 Application of Risk Management		-	Identical under single numbering
45	IS/ISO 22442-2 : 2015 ISO 22442-2 : 2015 ISO 22442-2:2007	Medical Devices Utilizing Animal Tissues and their Derivatives Part 2 Controls on Sourcing, Collection and Handling		-	Identical under single numbering
46	IS/ISO 22442-3 : 2007 ISO 22442-3:2007 ISO 22442-3:2007	Medical Devices Utilizing Animal Tissues and their Derivatives Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Spongiform Encephalopathy (TSE) Agents		-	Identical under single numbering
47	IS/ISO/TR 22442-4 : 2010 ISO/TR 22442-4:2010	Medical Devices Utilizing Animal Tissues and their Derivatives Part 4 Principles for Elimination and/or Inactivation of Transmissble Spongifrom Encephalopathy (TSE) Agents and Validation Assays for those Processes		-	Identical under single numbering

48	IS/ISO 23640 : 2011 ISO 23640 : 2011 ISO 23640 : 2011	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents		-	Identical under single numbering
49	IS/ISO/TR 37137 : 2014 ISO/TR 37137 : 2014 ISO/TR 37137:2014	Cardiovascular biological evaluation of medical devices - Guidance for absorbable implants		-	Identical under single numbering
50	IS/ISO 7405 : 2008 ISO 7405 : 2008 ISO 7405:2008	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry		-	Identical under single numbering

Standards under Development

Projects Approved

SI. No.	Doc No.	Title
1	MHD 19 (25234)	Blood Cell Counter Analyzer
2	MHD 19 (25235)	Hemoglobin Analyzer
3	MHD 19 (25236)	Biological evaluation of absorbable medical devices Part 1 General requirements
4	MHD 19 (25237)	Biological evaluation of medical devices Part 33 Guidance on tests to evaluate genotoxicity
5	MHD 19 (25238)	Biological evaluation of medical devices Part 55 Interlaboratory study on cytotoxicity
6	MHD 19 (26476)	Urine Analyzer

Preliminary Draft Standards

SI. No.	Doc No.	Title
No Records Found		

Drafts Standards in WC Stage

SI. No.	Doc No.	Title
No Records Found		

Draft Standards Completed WC Stage

SI. No.	Doc No.	Title
No Records Found		

Finalized Draft Indian Standard

SI. No.	Doc No.	Title
No Records Found		

Finalized Draft Indian Standards under Print

SI. No.	Doc No.	Title
1	MHD 19 (15611)	In-vitro Diagnostic IVD Devices - Blood Gas Analyzers

Total Published Standards:31 Total Standards Under development:7

Aspect Wise Report

Product : 10
Code of Practices : 1
Methods of Test : 35
Terminology : 0

Dimensions : 0
System Standard : 1
Safety Standard : 3
Others : 0
Service Specification : 0
Process Specification : 0
Unclassified : 0

Annexure-I :List of Indian Standards Withdrawn/Superseded

SI. No.	IS No. & Year	Title
1	IS/ISO 10993-1 : 2009 ISO 10993-1 : 2009 ISO 10993-1 : 2009	Biological evaluation of medical devices Part 1 Evaluation and Testing within a risk management process
2	IS/ISO 10993-9 : 2009 ISO 10993-9 : 2009 ISO 10993-9:2009	Biological evaluation of medical devices Part 9 Framework for identification and quantification of potential degradation products
3	IS/ISO 10993-10 : 2010 ISO 10993-10 : 2010 ISO 10993-10:2010	Biological evaluation of medical devices Part 10 Tests for irritation and skin sensitization
4	IS/ISO 10993-15 : 2000 ISO 10993-15 : 2000 ISO 10993-15:2000	Biological evaluation of medical devices Part 15 identification and quantification of degradation products from metals and alloys
5	IS/IEC/TS 10993-19 : 2006 ISO/TS 109993-19 : 2006 ISO/TS 109993-19 : 2006	Biological Evaluation of Medical Devices Part 19 Physico-Chemical Morphological and Topographical Characterization of Materials
6	IS 12024 : 1986 Reviewed In : 2006	Code of practice for field monitoring of movement of structures using tape extensometer
7	IS 12572 (Part 1) : 1994 ISO 10993-1 Reviewed In : 2016 ISO 10993-1	Biological Evaluation of Medical Devices - Part 1 Guidance on Selection of Tests
8	IS 12572 (Part 2) : 1995 ISO 10993-2 Reviewed In : 2016 ISO 10993-2	Biological evaluation of medical devices Part 2 animal welfare requirements
9	IS 12572 (Part 3) : 1988 Reviewed In : 2016	Guide for evaluation of medical devices for biological hazards Part 3 method of testing by tissue implantation
10	IS 12572 (Part 4) : 2016 ISO 10993-4 : 2002 ISO 10993-4 : 2002	Biological evaluation of medical devices Part 4 selection of tests for interaction with blood
11	IS 12572 (Part 5) : 1988 Reviewed In : 2016	Guide for evaluation of medical devices for biological hazards Part 5 method of test for intracutaneous reactivity of extracts from medical devices
12	IS 12572 (Part 6) : 1988 Reviewed In : 2016	Guide for evaluation of medical devices for biological hazards Part 6 method of test for systemic toxicity assessment of pyrogenicity in rabbits of extracts from medical devices
13	IS 12572 (Part 7) : 1988 Reviewed In : 2016	Guide for evaluation of medical devices for biological hazards Part 7 methods of test for sensitization assessment of potential of medical devices to produce delayed contact dermatitis
14	IS 12572 (Part 8) : 1988 Reviewed In : 2016	Guide forevaluationofmedical devices for biological hazards Part 8 method of test for skin irritation of extracts from medical devices
15	IS 12572 (Part 9) : 1988 Reviewed In : 2016	Guide for evaluation of medical devices for biological hazards Part 9 method of test for skin irritation by solid medical devices
16	IS 12572 (Part 10) : 1988 Reviewed In : 2016	Guide for Evaluation of Medical Devices for Biological Hazards Part 10 Biological Testing and Evaluation of Dental Materials
17	IS 12572 (Part 11) : 1990 Reviewed In : 2016	Guide for evaluation of medical devices for biological hazards Part 11 method of test for eye irritation
18	IS 12572 (Part 13) : 1995 ISO 10993-3 Reviewed In : 2016	Biological Evaluation of Medical Devices - Part 13 Tests for Genotoxicity Carcinogenicity and Reproductive Toxicity
19	IS 12572 (Part 14) : 1994	Biological Evaluation of Medical Devices - Part 14 Selection of Tests for Interactions with Blood

	ISO 10993-4 Reviewed In : 2016	
20	IS 13020 (Part 1) : 1991 Reviewed In : 2006	Medical Electrical Equipment - Ultrasonic Therapy Equipment - Part 1 Particular Requirements for the Safety
21	IS 13020 (Part 2) : 1990 Reviewed In : 2010	Medical Electrical Equipment - Ultrasonic Therapy Equipment - Part 2 Constructional and Performance Requirements
22	IS 13728 : 1993 IEC 520 Reviewed In : 2010	Entrance field sizes of elctro-optical X-ray image intensifiers
23	IS 13729 : 1993 IEC 572 Reviewed In : 2010	Determination of the luminance distribution of electro-optical X-ray image intensifiers
24	IS 13807 : 1994 IEC 788 Reviewed In : 2010	Medical radiology - Terminology
25	IS 13813 : 1993 Reviewed In : 2010	Measurement of the conversion factor of electro-optical X-ray image intensifiers
26	IS/IEC 61010-1 : 2010 IEC 61010-1 : 2010 IEC 61010-1:2010	Safety requirements for electrical equipment for measurement control and laboratory use Part 1 General requirements
27	IS/IEC 61010-2-081 : 2009 IEC 61010-2-081 : 2009 IEC 61010-2-81 : 2009	Safety Requirements for Electrical Equipment for Measurement Control and Laboratory Use Part 2-081 Particular Requirements for Automatic and Semi-automatic Laboratory Equipment for Analysis and Other Purposes
28	IS 7064 : 1973	Radiation protection in medical X-ray equipment operating at 10 kV to 400 kV
29	IS 8607 (Part 3) : 1978 Reviewed In : 1987	General and safety requirements for electrical equipment used in medical practice Part 3 Protection against mechanical hazards
30	IS 8607 (Part 4) : 1985 Reviewed In : 1991	General and safety requirements for electrical equipment used in medical practice Part 4 Protection against unwanted or excessive radiation
31	IS 8607 (Part 5) : 1983	General and Safety Requirements for Electrical Equipment Used in Medical Practice - Part 5 Protection Against Explosion Hazards
32	IS 8607 (Part 6) : 1984 Reviewed In : 1991	General and safety requirements for electrical equipment used in medical practice Part 6 Protection against excessive temperatures fire and other hazards
33	IS 8607 (Part 7) : 1985 Reviewed In : 1991	General and safety requirements for electrical equipment used in medical practice Part 7 Construction
34	IS 8607 (Part 8) : 1985 Reviewed In : 1991	General and safety requirements for electrical equipment used in medical practice Part 8 Behaviour and reliability
35	IS 8902 : 1978	Area exposure product meter
36	IS 9286 (Part 2) : 1988 Reviewed In : 2010	Cardiac Defibrillators - Part 2 Construction and Performance Requirements

Annexure-II :List of Indian Product Standards

SI. No.	IS No. & Year	Title
1	IS 17713 : 2023	In-Vitro Diagnostic Devices - ELISA Plate Reader
2	IS 17714 : 2023	In-Vitro Diagnostic Devices - Automated ELISA Processor
3	IS 17715 : 2023	In-vitro Diagnostic Device - ELISA Plate Washer
4	IS 17717 (Part 1) : 2023	In-Vitro Diagnostic Device - Automated Clinical chemistry Analyzer - Part 1 Wet Chemistry Analyzer
5	IS 17717 (Part 2) : 2023	In-Vitro Diagnostic IVD Device - Automated Clinical Chemistry Analyzer Part 2 Dry Chemistry Analyzer
6	IS 17718 : 2022 ISO 7206-13: 2016	Performance testing of In-vitro Diagnostics IVD Reagent Kit alpha - Amylase CNP-G3 Liquid Stable Clinical Chemistry Reagents Kits
7	IS 17719 : 2023	In-Vitro Diagnostic IVD Medical Device - Automatic Slide Staining Instrument

8	IS 17720 : 2023	In-vitro Diagnostic Device - Automated Blood Culture and Microbial Detection System
9	IS 17721 : 2024	In-vitro Diagnostic IVD Devices - Electrolyte Analyzer
10	IS 17724 (Part 1) : 2023 61010-1	Safety Requirements for Electrical Equipment for Measurement Control and Laboratory Use Part 1 General Requirements IEC 61010-1 2010 AMD1 2016 COR1 2019 MOD