

## 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* **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 <span style="color: green;">ISO 10993-2:2006</span>	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 <span style="color: green;">ISO 10993-3 : 2014</span>	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 <span style="color: green;">ISO 10993-4 : 2017</span>	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 <span style="color: green;">ISO 10993-5 : 2009</span>	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 <span style="color: green;">ISO 10993-6 : 2016</span>	Biological evaluation of medical devices Part 6 Tests for local effects after implantation		-	Identical under single numbering
6	IS/ISO 10993-11:2017 ISO 10993-11 : 2017 <span style="color: green;">ISO 10993-11 : 2017</span>	Biological evaluation of medical devices Part 11 Tests for systemic toxicity		-	Identical under single numbering
7	IS/ISO 10993-12:2021 10993: Part 12 <span style="color: green;">ISO 10993-12:2021</span>	Biological Evaluation of Medical Devices Part 12 Sample Preparation and Reference Materials		-	Identical under single numbering
8	IS/ISO 10993-13:2010 ISO 10993-13:2010	Biological evaluation of medical devices Part 13 Identification and quantification of degradation		-	Identical under single numbering

	ISO 10993-13:2010	products from polymeric medical devices			
9	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
10	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
11	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
12	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
13	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
14	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
15	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
16	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
17	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
18	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
19	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
20	IS/ISO 17511:2020 ISO 17511 : 2020 ISO 17511:2020	In Vitro Diagnostic Medical Devices - Requirements for Establishing Metrological Traceability of Values Assigned to		-	Identical under single numbering

		Calibrators, Trueness Control Materials and Human Samples			
21	IS 17713:2023	In-Vitro Diagnostic Devices - ELISA Plate Reader		-	Indigenous
22	IS 17714:2023	In-Vitro Diagnostic Devices - Automated ELISA Processor		-	Indigenous
23	IS 17715:2023	In-vitro Diagnostic Device - ELISA Plate Washer		-	Indigenous
24	IS 17716:2024	In-vitro Diagnostic (IVD) Devices - Blood Gas Analyzers		-	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 IEC 61326-1: 2020	Electrical Equipment for Measurement, Control and Laboratory Use - EMC		-	Modified/Technically Equivalent

		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 Transmissible Spongiform Encephalopathy (TSE) Agents and Validation Assays for those Processes		-	Identical under single numbering
48	IS/ISO 23640:2011	In vitro diagnostic medical devices		-	Identical under single

	ISO 23640 : 2011 ISO 23640 : 2011	- Evaluation of stability of in vitro diagnostic reagents			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
<i>No Records Found</i>		

#### Drafts Standards in WC Stage

SI. No.	Doc No.	Title
<i>No Records Found</i>		

#### Draft Standards Completed WC Stage

SI. No.	Doc No.	Title
<i>No Records Found</i>		

#### Finalized Draft Indian Standard

SI. No.	Doc No.	Title
<i>No Records Found</i>		

#### Finalized Draft Indian Standards under Print

SI. No.	Doc No.	Title
1	MHD 19 (00270)	Biological evaluation of medical devices- Part 1 Evaluation and testing within a risk Management process
2	MHD 19 (00338)	Biological evaluation of medical devices -- Part 10 Tests for irritation and skin sensitization
3	MHD 19 (00369)	Biological evaluation of medical devices-Part 7 Ethylene oxide Sterilization residuals
4	MHD 19 (00370)	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
5	MHD 19 (00315)	Safety Requirements for Electrical Equipment For Measurement Control and Laboratory Use Part 1 General Requirements
6	MHD 19 (00290)	Biological evaluation of medical devices -- Part 20 Principles and methods for immunotoxicology testing of medical devices
7	MHD 19 (00271) Revision of: IS 12572:1995	Biological Evaluation of Medical Devices Part 2 Animal Welfare Requirements First Revision

8	MHD 19 (00274)	Biological evaluation of medical devices -- Part 5 Tests for in vitro cytotoxicity
9	MHD 19 (00291)	Clinical investigation of medical devices for human subjects- Good Clinical Practice
10	MHD 19 (00444)	Biological evaluation of medical devices -- Part 4 Selection of tests for interactions with blood Amendment No 1
11	MHD 19 (00445)	Biological evaluation of medical devices -- Part 9 Framework for identification and quantification of potential degradation products
12	MHD 19 (00446)	Biological evaluation of medical devices -- Part 13 Identification and quantification of degradation products from polymeric medical devices
13	MHD 19 (00447)	Biological evaluation of medical devices -- Part 14 Identification and quantification of degradation products from ceramics
14	MHD 19 (00448)	Biological evaluation of medical devices -- Part 15 Identification and quantification of degradation products from metals and alloys
15	MHD 19 (00450)	Biological evaluation of medical devices -- Part 17 Establishment of allowable limits for leachable substances
16	MHD 19 (00483)	Biological evaluation of medical devices -- Part 19 Physico-chemical morphological and topographical characterization of materials
17	MHD 19 (00484)	Medical products containing viable human cells -- Application of risk management and requirements for processing practices
18	MHD 19 (00486)	Biological evaluation of medical devices -- Guidance on the conduct of biological evaluation within a risk management process
19	MHD 19 (00487)	Medical devices utilizing animal tissues and their derivatives -- Part 2 Controls on sourcing collection and handling
20	MHD 19 (00488)	Medical devices utilizing animal tissues and their derivatives -- Part 4 Principles for elimination and or inactivation of transmissible spongiform encephalopathy TSE agents and validation assays for those processes
21	MHD 19 (10352)	Biological evaluation of medical devices-Part 3 Tests for genotoxicity carcinogenicity and reproductive toxicity
22	MHD 19 (11487)	Biological Evaluation of Medical Devices Part 4 Selection of Tests for Interaction with Blood First Revision Amendment - 1
23	MHD 19 (12940)	Biological evaluation of medical devices Part 6 Tests for local effects after implantation
24	MHD 19 (12941)	Biological evaluation of medical devices Part 11 Tests for systemic toxicity
25	MHD 19 (12942)	Biological evaluation of medical devices Part 16 Toxicokinetic study design for degradation products and leachables
26	MHD 19 (12943)	Medical devices utilizing animal tissues and their derivatives Part 1 Application of risk management
27	MHD 19 (12944)	Medical devices utilizing animal tissues and their derivatives Part 2 Controls on sourcing collection and handling
28	MHD 19 (12945)	Biological evaluation of medical devices Guidance on the conduct of biological evaluation within a risk management process
29	MHD 19 (12986) Revision of: IS 12572:2016	Biological evaluation of medical devices Part 4 Selection of tests for interactions with blood Second Revision
30	MHD 19 (13646)	Biological evaluation of medical devices Part 22 Guidance on nano-materials
31	MHD 19 (15611)	In-vitro Diagnostic IVD Devices - Blood Gas Analyzers
32	MHD 19 (15612)	In-Vitro Diagnostic Device - Automated Clinical chemistry Analyzer - Part 1 Wet Chemistry Analyzer
33	MHD 19 (15613)	In-vitro Diagnostic IVD Devices - Electrolyte Analyzer
34	MHD 19 (15616)	In-Vitro Diagnostic Devices - ELISA Plate Reader
35	MHD 19 (15617)	In-Vitro Diagnostic Devices - Automated ELISA Processor
36	MHD 19 (15618)	Performance testing of In-vitro Diagnostics IVD Reagents Kits -Amylase CNP-G3 Liquid Stable Clinical Chemistry Reagents Kits
37	MHD 19 (16146)	In-Vitro Diagnostic IVD Medical Device - Automatic Slide Staining Instrument
38	MHD 19 (16147)	In-Vitro Diagnostic IVD Device - Automated Clinical Chemistry Analyzer Part 2 Dry Chemistry Analyzer
39	MHD 19 (16241)	In-vitro Diagnostic Device - Automated Blood Culture and Microbial Detection System
40	MHD 19 (16248)	In-vitro Diagnostic Device - ELISA Plate Washer
41	MHD 19 (16623)	Biological evaluation of medical devices Part 1 Evaluation and testing within a risk management process
42	MHD 19 (17262)	Biological evaluation of medical devices Part 18 Chemical characterization of medical device materials within a risk management process

43	MHD 19 (17263)	Biological evaluation of medical devices Part 12 Sample preparation and reference materials
44	MHD 19 (17306)	Safety Requirements for Electrical Equipment for Measurement Control And Laboratory Use Part 2 Particular Requirements for Laboratory Equipment used in Mixing and Stirring
45	MHD 19 (17307)	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
46	MHD 19 (17308)	Safety Requirements for Electrical Equipment for Measurement Control and Laboratory Use Part 4 Particular Requirements for In-Vitro Diagnostic IVD Medical Equipment
47	MHD 19 (17309)	Electrical equipment for measurement control and laboratory use - EMC requirements Part 2 Particular requirements for In-vitro diagnostic IVD medical equipment
48	MHD 19 (20252)	Biological Evaluation of Medical Devices Part 2 Framework for identification and quantification of potential degradation products
49	MHD 19 (20253)	Biological Evaluation of Medical Devices Part 6 Tests for skin sensitization
50	MHD 19 (20256)	Biological Evaluation of Medical Devices Part 3 Identification and quantification of degradation products from metals and alloys
51	MHD 19 (20260)	Biological Evaluation of Medical Devices Part 4 Physico-chemical morphological and topographical characterization of materials
52	MHD 19 (20261) Revision of: IS/ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
53	MHD 19 (21334)	Electrical Equipment for Measurement Control and Laboratory Use EMC Requirements Part 1 General Requirements IEC 61326-1 2020 MOD
54	MHD 19 (21362)	Safety Requirements for Electrical Equipment for Measurement Control and Laboratory Use Part 1 General Requirements IEC 61010-1 2010 AMD1 2016 COR1 2019 MOD
55	MHD 19 (21867)	Biological Evaluation of Medical Devices Part 5 Ethylene oxide sterilization residuals
56	MHD 19 (22473)	Biological Evaluation of Medical Devices Part 7 Tests for irritation ISO 10993-23 2021 MOD

**Total Published Standards:30 Total Standards Under development:62**

### Aspect Wise Report

Product : 11  
Code of Practices : 1  
Methods of Test : 34  
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 10993-7:2018 ISO 10993-7 : 2008 ISO 10993-7:2008	Biological evaluation of medical devices Part 7 Ethylene oxide sterilization residuals
3	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
4	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
5	IS/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

	ISO 10993-15:2000	
6	IS/IEC/TS 10993-19:2006 ISO/TS 10993-19 : 2006 ISO/TS 10993-19 : 2006	Biological Evaluation of Medical Devices Part 19 Physico-Chemical Morphological and Topographical Characterization of Materials
7	IS 12024:1986 Reviewed In : 2006	Code of practice for field monitoring of movement of structures using tape extensometer
8	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
9	IS 12572 (Part 2):1995 ISO 10993-2 Reviewed In : 2016 ISO 10993-2	Biological evaluation of medical devices Part 2 animal welfare requirements
10	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
11	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
12	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
13	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
14	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
15	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
16	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
17	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
18	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
19	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
20	IS 12572 (Part 14):1994 ISO 10993-4 Reviewed In : 2016	Biological Evaluation of Medical Devices - Part 14 Selection of Tests for Interactions with Blood
21	IS 13020 (Part 1):1991 Reviewed In : 2006	Medical Electrical Equipment - Ultrasonic Therapy Equipment - Part 1 Particular Requirements for the Safety
22	IS 13020 (Part 2):1990 Reviewed In : 2010	Medical Electrical Equipment - Ultrasonic Therapy Equipment - Part 2 Constructional and Performance Requirements
23	IS 13728:1993 IEC 520 Reviewed In : 2010	Entrance field sizes of electro-optical X-ray image intensifiers
24	IS 13729:1993 IEC 572 Reviewed In : 2010	Determination of the luminance distribution of electro-optical X-ray image intensifiers
25	IS 13807:1994 IEC 788 Reviewed In : 2010	Medical radiology - Terminology
26	IS 13813:1993 Reviewed In : 2010	Measurement of the conversion factor of electro-optical X-ray image intensifiers
27	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
28	IS/IEC 61010-2-081:2009 IEC 61010-2-081 : 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

	IEC 61010-2-81 : 2009	Analysis and Other Purposes
29	IS 7064:1973	Radiation protection in medical X-ray equipment operating at 10 kV to 400 kV
30	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
31	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
32	IS 8607 (Part 5):1983	General and Safety Requirements for Electrical Equipment Used in Medical Practice - Part 5 Protection Against Explosion Hazards
33	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
34	IS 8607 (Part 7):1985 Reviewed In : 1991	General and safety requirements for electrical equipment used in medical practice Part 7 Construction
35	IS 8607 (Part 8):1985 Reviewed In : 1991	General and safety requirements for electrical equipment used in medical practice Part 8 Behaviour and reliability
36	IS 8902:1978	Area exposure product meter
37	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 17716:2024	In-vitro Diagnostic IVD Devices - Blood Gas Analyzers
5	IS 17717 (Part 1):2023	In-Vitro Diagnostic Device - Automated Clinical chemistry Analyzer - Part 1 Wet Chemistry Analyzer
6	IS 17717 (Part 2):2023	In-Vitro Diagnostic IVD Device - Automated Clinical Chemistry Analyzer Part 2 Dry Chemistry Analyzer
7	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
8	IS 17719:2023	In-Vitro Diagnostic IVD Medical Device - Automatic Slide Staining Instrument
9	IS 17720:2023	In-vitro Diagnostic Device - Automated Blood Culture and Microbial Detection System
10	IS 17721:2024	In-vitro Diagnostic IVD Devices - Electrolyte Analyzer
11	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