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:	Biological Evaluation of Medical		-	Identical under single
	2006	Devices Part 2 Animal Welfare			numbering
	ISO 10993-2:2006	Requirements (First Revision)			
	ISO 10993-2:2006				
2	IS/ISO 10993-3:	Biological evaluation of medical		-	Identical under single
	2014	devices Part 3 Tests for			numbering
	ISO 10993-3 : 2014	Genotoxicity, Carcinogenicity and			
	ISO 10993-3: 2014	Reproductive toxicity (First			
		Revision)			
3	IS/ISO 10993-4:	Biological evaluation of medical		-	Identical under single
	2017	devices Part 4 Selection of tests for			numbering
	ISO 10993-4 : 2017	interactions with blood			
	ISO 10993-4:2017				
4	IS/ISO 10993-5:	Biological evaluation of medical		-	Identical under single
	2009	devices Part 5 Tests for in vitro			numbering
	ISO 10993-5 : 2009	cytotoxicity			
	ISO 10993-5: 2009				
5	IS/ISO 10993-6:	Biological evaluation of medical		-	Identical under single
	2016	devices Part 6 Tests for local			numbering
	ISO 10993-6 : 2016	effects after implantation			
	ISO 10993-6: 2016				
6	IS/ISO 10993-7:	Biological evaluation of medical		-	Identical under single
	2018	devices Part 7 Ethylene oxide			numbering
	ISO 10993-7 : 2008	sterilization residuals			
	ISO 10993-7:2008				
7	IS/ISO 10993-9:	Biological evaluation of medical		-	Identical under single
	2009	devices Part 9 Framework for			numbering
	ISO 10993-9 : 2009	identification and quantification of			
	ISO 10993-9:2009	potential degradation products			
8	IS/ISO 10993-11:	Biological evaluation of medical		-	Identical under single
	2017	devices Part 11 Tests for systemic			numbering
	ISO 10993-11 : 2017	toxicity			
	ISO 10993-11:				
	2017				
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10		10993: Part 12	_			
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13		ISO 10993-15 : 2000	quantification of degradation			
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180 10993-16 : 2017						numbering
14			, ,			
14		ISO 10993-16:	Products and Leachables			
Devices Part 17 Establishment of ISO 10993-17 : 2002 Allowabe Limits for Leachable Substances Substances Substances						
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15 IS/ISO 10993-18: 2020			Allowable Limits for Leachable			
15 IS/ISO 10993-18 Biological evaluation of medical devices Part 18 Chemical Characterization of medical device Part 18 Chemical Characterization of medical device SO 10993-18:2020 Devices Part 19 Physico-Chemical, ISO/TS 109993-19 Devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices Part 20 Principles and methods for immunotoxicology testing of medical device			Substances			
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16		ISO 10993-18:2020	materials within a risk management			
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	Reviewed In : 2020	ر ج			
	ISO 15197 : 2013	Testing in Managing Diabetes			
	10/100 15100 2004	Mellitus (First Revision)			T1 .: 1 1 : 1
22	IS/ISO 15198 : 2004	_		=	Identical under single
	ISO 15198 : 2004	vitro Diagnostic Medical Devices -			numbering
	ISO 15198:2004	Validation of User Quality Control			
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23	IS/ISO/TR 15499 :	Biological evaluation of medical		-	Identical under single
	2016	devices - Guidance on the conduct			numbering
	ISO/TR 15499 :	of biological evaluation within a			
	2016	risk management process			
	ISO/TR 15499:				
	2016				*1 1 1 1 1
24	IS/ISO 17511 : 2020	٤		-	Identical under single
	ISO 17511 : 2020	Devices - Requirements for			numbering
	ISO 17511:2020	Establishing Metrological			
		Traceability of Values Assigned to			
		Calibrators, Trueness Control			
		Materials and Human Samples			
25	IS 17713 : 2023	In-Vitro Diagnostic Devices -		-	Indigenous
		ELISA Plate Reader			
26	IS 17714 : 2023	In-Vitro Diagnostic Devices -		-	Indigenous
		Automated ELISA Processor			
27	IS 17715 : 2023	In-vitro Diagnostic Device -		-	Indigenous
		ELISA Plate Washer			
28	IS 17717 (Part 1):	In-Vitro Diagnostic Device -		=	Indigenous
	2023	Automated Clinical chemistry			
		Analyzer - Part 1 Wet Chemistry			
		Analyzer			
29		In-Vitro Diagnostic (IVD) Device -		-	Indigenous
	2023	Automated Clinical Chemistry			
		Analyzer Part 2 Dry Chemistry			
		Analyzer			
30	IS 17718 : 2022	Performance testing of In-vitro		-	Indigenous
		Diagnostics IVD Reagent Kit alpha			
		- Amylase CNP-G3 Liquid Stable			
		Clinical Chemistry Reagents/ Kits			
31	IS 17719 : 2023	In-Vitro Diagnostic (IVD) Medical		-	Indigenous
		Device - Automatic Slide Staining			
		Instrument			
32	IS 17720 : 2023	In-vitro Diagnostic Device -		-	Indigenous
		Automated Blood Culture and			
		Microbial Detection System			
33	, , , , , , , , , , , , , , , , , , , ,	Safety Requirements for Electrical		-	Modified/Technically
	2023	Equipment for Measurement,			Equivalent
		Control, and Laboratory Use Part 1			
	+ AMD1:2016 +	General Requirements (IEC			
	COR1:2019	61010-1: 2010 + AMD1:2016 +			
		COR1:2019, MOD)			
34		Safety Requirements for Electrical		-	Identical under dual
	2023	Equipment for Measurement,			numbering
	IEC 61010-2-051:	Control, And Laboratory Use Part			
	2018	2 Particular Requirements for			
	IEC 61010-2-051:	Laboratory Equipment used in			
	2018	Mixing and Stirring			
35		Safety Requirements for Electrical		-	Modified/Technically
	2024	Equipment for Measurement,			Equivalent
	IEC 61010-2-081:	Control, And Laboratory Use Part			
	2019	3 Particular Requirements of			
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		Automatic and Semi-Automatic			
		Laboratory Equipment used for			
		Analysis and Other Purposes			
36	IS 17724 (Part 4):	Safety Requirements for Electrical		-	Modified/Technically
	2023	Equipment for Measurement,			Equivalent
	IEC 61010-2-101:	Control, and Laboratory Use Part 4			
	2018	Particular Requirements for In-			
		Vitro Diagnostic (IVD) Medical			
		Equipment (IEC 61010-2-101 :			
		2018, MOD)			
37	IS 17784 (Part 1):	Electrical Equipment for		-	Modified/Technically
	2023	Measurement, Control and			Equivalent
	IEC 61326-1: 2020	· · · · · · · · · · · · · · · · · · ·			1
		Requirements Part 1 General			
		Requirements (IEC 61326-1: 2020,			
		MOD)			
38	IS 17784 (Part 2):	Electrical equipment for		_	Modified/Technically
	2023	measurement, control and			Equivalent
		laboratory use - EMC requirements			Equivalent
	2020	Part 2 Particular requirements for			
	2020	-			
		In-vitro diagnostic (IVD) medical			
		equipment (IEC 61326-2-6 : 2020,			
20	TG 15000 (D + 1)	MOD)			N. 1.C. 1/22 1 . 11
39	IS 17932 (Part 1):	Biological evaluation of medical		=	Modified/Technically
	2023	devices Part 1: Evaluation and			Equivalent
	ISO 10993-1:2018	testing within a risk management			
		process (ISO 10993-1 : 2018,			
		MOD)			
40	IS 17932 (Part 2):	Biological Evaluation of Medical		=	Modified/Technically
	2024	Devices Part 2 Framework for			Equivalent
	ISO 10993-9: 2019	identification and quantification of			
		potential degradation products			
41	IS 17932 (Part 3):	Biological Evaluation of Medical		-	Modified/Technically
	2024	Devices Part 3 Identification and			Equivalent
	ISO 10993-15: 2019	quantification of degradation			
		products from metals and alloys			
42	IS 17932 (Part 4):	Biological Evaluation of Medical		-	Modified/Technically
	2024	Devices Part 4 Physico-chemical			Equivalent
	ISO 10993-19: 2020	morphological and topographical			
		characterization of materials			
43	IS 17932 (Part 6):	Biological Evaluation of Medical		-	Modified/Technically
	2023	Devices Part 6 Tests for skin			Equivalent
	ISO 10993-10: 2021	sensitization (ISO 10993-10 : 2021,			1
		MOD)			
44	IS/ISO 22442-1:	Medical Devices Utilizing Animal		_	Identical under single
1	2015	Tissues and their Derivatives Part 1			numbering
	ISO 22442-1 : 2015	Application of Risk Management			
	ISO 22442-1 : 2015				
45	IS/ISO 22442-2 :	Medical Devices Utilizing Animal		_	Identical under single
"	2015	Tissues and their Derivatives Part 2		_	numbering
	ISO 22442-2 : 2015	Controls on Sourcing, Collection			numbering
	ISO 22442-2:2007	and Handling			
16	IS/ISO 22442-2:2007	Medical Devices Utilizing Animal			Identical under single
46				-	Identical under single
	2007	Tissues and their Derivatives Part 3			numbering
	ISO 22442-3:2007	Validation of the Elimination			
	ISO 22442-3:2007	and/or Inactivation of Viruses and			
		Transmissible Spongiform			
<u></u>		Encephalopathy (TSE) Agents			
47	IS/ISO/TR 22442-4 :	Medical Devices Utilizing Animal		-	Identical under single
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	2010	Tissues and their Derivatives Part 4		numbering
		Principles for Elimination and/or		
	ISO/TR Inactivation of Transmissble			
	22442-4:2010 Spongifrom Encephalopathy (TSE)			
		Agents and Validation Assays for		
		those Processes		
48	IS/ISO 23640 : 2011	In vitro diagnostic medical devices	-	Identical under single
	ISO 23640 : 2011	- Evaluation of stability of in vitro		numbering
	ISO 23640 : 2011	diagnostic reagents		
49	IS/ISO/TR 37137:	Cardiovascular biological	-	Identical under single
	2014	evaluation of medical devices -		numbering
	ISO/TR 37137:	Guidance for absorbable implants		
	2014			
	ISO/TR 37137:2014			
50	IS/IEC 61010-2-081	Safety Requirements for Electrical	-	Identical under single
	: 2009	Equipment for Measurement,		numbering
	IEC 61010-2-081:	Control and Laboratory Use Part		
	2009	2-081 Particular Requirements for		
	IEC 61010-2-81:	Automatic and Semi-automatic		
	2009	Laboratory Equipment for Analysis		
		and Other Purposes		
51	IS/ISO 7405 : 2008	Dentistry - Evaluation of	-	Identical under single
	ISO 7405 : 2008	biocompatibility of medical		numbering
	ISO 7405:2008	devices used in dentistry		

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			

	Preliminary Draft Standards					
SI. No.	SI. No. Doc No. Title					
No Records Found						

	Drafts Standards in WC Stage				
SI. No.	SI. No. Doc No. Title				
No Records Found					

	Draft Standards Completed WC Stage				
SI. No.	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
2	MHD 19 (15613)	In-vitro Diagnostic IVD Devices - Electrolyte Analyzer
3	MHD 19 (21867)	Biological Evaluation of Medical Devices Part 5 Ethylene oxide sterilization residuals
4	MHD 19 (22473)	Biological Evaluation of Medical Devices Part 7 Tests for irritation ISO 10993-23 2021 MOD

Total Published Standards:34 Total Standards Under development:9

Aspect Wise Report

Product: 9
Code of Practices: 1
Methods of Test: 36
Terminology: 0
Dimensions: 0
System Standard: 1
Safety Standard: 4
Others: 0
Service Specification: 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	Biological evaluation of medical devices Part 1 Evaluation and Testing within a risk management
	ISO 10993-1:2009	process
	ISO 10993-1 : 2009	
2	IS/ISO 10993-10 : 2010	Biological evaluation of medical devices Part 10 Tests for irritation and skin sensitization
	ISO 10993-10 : 2010	
	ISO 10993-10:2010	
3	IS 12024 : 1986	Code of practice for field monitoring of movement of structures using tape extensometer
	Reviewed In: 2006	
4	IS 12572 (Part 1): 1994	Biological Evaluation of Medical Devices - Part 1 Guidance on Selection of Tests
	ISO 10993-1	
	Reviewed In: 2016 ISO	
	10993-1	
5	IS 12572 (Part 2): 1995	Biological evaluation of medical devices Part 2 animal welfare requirements
	ISO 10993-2	
	Reviewed In: 2016 ISO	
	10993-2	
6	IS 12572 (Part 3): 1988	Guide for evaluation of medical devices for biological hazards Part 3 method of testing by tissue
	Reviewed In: 2016	implantation
7	IS 12572 (Part 4): 2016	Biological evaluation of medical devices Part 4 selection of tests for interaction with blood
	ISO 10993-4 : 2002	
	ISO 10993-4 : 2002	
8	IS 12572 (Part 5): 1988	Guide for evaluation of medical devices for biological hazards Part 5 method of test for
	Reviewed In: 2016	intracutaneous reactivity of extracts from medical devices
9	IS 12572 (Part 6): 1988	Guide for evaluation of medical devices for biological hazards Part 6 method of test for systemic
	Reviewed In: 2016	toxicity assessment of pyrogenicity in rabbits of extracts from medical devices
10	IS 12572 (Part 7): 1988	Guide for evaluation of medical devices for biological hazards Part 7 methods of test for
	Reviewed In: 2016	sensitization assessment of potential of medical devices to produce delayed contact dermatitis
11	IS 12572 (Part 8): 1988	Guide forevaluationofmedical devices for biological hazards Part 8 method of test for skin
	Reviewed In: 2016	irritation of extracts from medical devices
12	IS 12572 (Part 9): 1988	Guide for evaluation of medical devices for biological hazards Part 9 method of test for skin
	Reviewed In: 2016	irritation by solid medical devices
13	IS 12572 (Part 10): 1988	Guide for Evaluation of Medical Devices for Biological Hazards Part 10 Biological Testing and
	Reviewed In: 2016	Evaluation of Dental Materials
14	IS 12572 (Part 11): 1990	Guide for evaluation of medical devices for biological hazards Part 11 method of test for eye

1	Reviewed In: 2016	irritation
15	IS 12572 (Part 13): 1995	Biological Evaluation of Medical Devices - Part 13 Tests for Genotoxicity Carcinogenicity and
	ISO 10993-3	Reproductive Toxicity
	Reviewed In: 2016	T Tank to S
16	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	
17	IS 13020 (Part 1): 1991	Medical Electrical Equipment - Ultrasonic Therapy Equipment - Part 1 Particular Requirements
	Reviewed In: 2006	for the Safety
18	IS 13020 (Part 2): 1990	Medical Electrical Equipment - Ultrasonic Therapy Equipment - Part 2 Constructional and
	Reviewed In: 2010	Performance Requirements
19	IS 13728 : 1993	Entrance field sizes of elctro-optical X-ray image intensifiers
	IEC 520	
	Reviewed In: 2010	
20	IS 13729 : 1993	Determination of the luminance distribution of electro-optical X-ray image intensifiers
	IEC 572	
	Reviewed In: 2010	
21	IS 13807 : 1994	Medical radiology - Terminology
	IEC 788	
	Reviewed In: 2010	
22	IS 13813 : 1993	Measurement of the conversion factor of electro-optical X-ray image intensifiers
	Reviewed In: 2010	
23	IS/IEC 61010-1 : 2010	Safety requirements for electrical equipment for measurement control and laboratory use Part 1
	IEC 61010-1 : 2010	General requirements
	IEC 61010-1:2010	
24	IS 7064 : 1973	Radiation protection in medical X-ray equipment operating at 10 kV to 400 kV
25	IS 8607 (Part 3): 1978	General and safety requirements for electrical equipment used in medical practice Part 3
	Reviewed In: 1987	Protection against mechanical hazards
26	IS 8607 (Part 4): 1985	General and safety requirements for electrical equipment used in medical practice Part 4
	Reviewed In: 1991	Protection against unwanted or excessive radiation
27	IS 8607 (Part 5): 1983	General and Safety Requirements for Electrical Equipment Used in Medical Practice - Part 5
		Protection Against Explosion Hazards
28	IS 8607 (Part 6): 1984	General and safety requirements for electrical equipment used in medical practice Part 6
	Reviewed In: 1991	Protection against excessive temperatures fire and other hazards
29	IS 8607 (Part 7): 1985	General and safety requirements for electrical equipment used in medical practice Part 7
	Reviewed In: 1991	Construction
30	IS 8607 (Part 8): 1985	General and safety requirements for electrical equipment used in medical practice Part 8
	Reviewed In: 1991	Behaviour and reliability
31	IS 8902 : 1978	Area exposure product meter
32	IS 9286 (Part 2): 1988	Cardiac Defibrillators - Part 2 Construction and Performance Requirements
	Reviewed In: 2010	

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 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