Doc No: MHD 19(338)
IS/ISO 10993-10 : 2010

भारतीय मानक

चिकित्सा उपकरणों के जैविक मूल्यांकन

भाग 10 जलन और त्वचा संवेदनशील बनाने के लिए परीक्षण

Indian Standard

BIOLOGICAL EVALUATION OF MEDICAL DEVICES

Part 10 Tests for Irritation and Skin Sensitization

ICS 11.100.20

B U R E A U O F I N D I A N S T A N D A R D S
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Immuno-Biological Diagnostic Kits Sectional Committee, MHD 19

NATIONAL FOREWORD

This Indian Standard (Part 10) which is identical with ISO 10993-10 : 2010 'Biological evaluation of medical devices — Part 10 Tests for irritation and skin sensitization' was adopted by the Bureau of Indian Standards on the recommendation of Immuno Biological Diagnostic Kits Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This part of standard assesses possible contact hazards from chemicals released from medical devices which may produce skin and mucosal irritation, eye irritation or skin sensitization.

Some materials that are included in medical devices have been tested, and skin or mucosal irritation or sensitization potential has been documents. Other materials and their chemical components have not been tested and may induce adverse effects when in contact with human tissue.

Traditionally, small animal tests are performed prior to testing on humans to help predict human response. More recently, in vitro tests as well as human tests have been added as adjuncts or alternatives. Despite progress and considerable effort in this direction, a review of findings suggests that currently no satisfactory in vitro test has been devised to eliminate the requirement for in vivo testing. Where appropriate, the preliminary use of in vitro methods is encouraged for screening purposes prior to animal testing. In order to reduce the number of animals used, this part of IS/ISO 10993 present a step-wise approach, with review and analysis of test results at each stage. An animal test is usually required prior to human testing.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 10993-1 : 2009 Biological evaluation of medical devices- Part1: Evaluation and testing within a risk management process	IS/ISO 10993-1 : 2009 Biological evaluation of medical devices Part1 : Evaluation and testing within a risk management process (*Under*	Identical with ISO 10993-1 : 2009

	publication)	
International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 10993-2 Biological evaluation of medical devices — Part 2: Animal welfare requirements	IS/ISO 10993 : 2006 Biological evaluation of medical devices : Part 2 Animal welfare requirements (*Under publication*)	Identical with ISO 10993-2 : 2006
ISO 10993-9 Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation product	IS/ISO 10993-9 : 2009 Biological evaluation of medical devices : Part 9 Framework for identification and quantification of potential degradation product (*Under publication*)	Identical with ISO 10993-9 : 2009
ISO 10993-12 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	IS/ISO 10993-12 : 2012 Biological evaluation of medical devices : Part 12 Sample preparation and reference materials *(Under publication)*	Identical with ISO 10993-12 : 2012
ISO 10993-13 Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical device	IS/ISO 10993-13 : 2010 Biological evaluation of medical devices : Part 13 Identification and quantification of degradation products from polymeric medical device (*Under publication*)	Identical with ISO 10993-13 : 2010
ISO 10993-14 Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics	IS/ISO 10993-14 : 2001 Biological evaluation of medical devices : Part 14 Identification and quantification of degradation products from ceramics *(Under publication)*	Identical with ISO 10993-14 : 2001
ISO 10993-15 Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloy	IS/ISO 10993-15 : 2000 Biological evaluation of medical devices : Part 15 Identification and quantification of degradation products from metals and alloy *(Under publication)*	Identical with ISO 10993-15 : 2000
ISO 10993-18 : 2005 Biological evaluation of medical devices — Part 18: Chemical characterization of materials	IS/ISO 10993-18 : 2005 Biological evaluation of medical devices : Part 18 Chemical characterization of materials *(Under publication)*	Identical

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 14155-1 : 2003[1)] Clinical investigation of medical devices for human subjects — Part 1: General requirements	IS/ISO 14155 : 2011 Chemical investigation of medical devices for human subjects — Good clinical practice *(Under publication)*	Identical with ISO 14155 : 2011
ISO 14155-2 : 2003[1)] Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans		

1) Since revised as IS 14155 : 2011 'Clinical investigation of medical devices for human subjects — Good clinical practice'.