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BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

न्यूरोसर्जिकल अन्त्यरोपन - स्व-समापन इंट्राक्रैनियल एन्यूरिज्म क्लिप

(ISO 9713: 2022)

Draft Indian Standard

Neurosurgical Implants — Self Closing Intracranial Aneurysm Clips

(ISO 9713: 2022)

[ICS: 11.040.40]

Neurosurgery Instruments Implants And Accessories Sectional Committee (MHD 07)	Last Date for Comments: **24 July 2024**

NATIONAL FOREWORD

(Adoption clause will be added later)

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 Standard*	*Degree of Equivalence*
ISO 5832-2, Implants for surgery — Metallic materials — Part 2: Unalloyed titanium	IS/ISO 5832-(Part 2) , Implants for Surgery — Metallic Materials Part 2 Unalloyed Titanium (First Revision)	Identical
ISO 5832-3, Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	IS 18261 (Part 3) , Implants for Surgery — Metallic Materials Part 3 Wrought Titanium 6-Aluminium 4-Vanadium Alloy (Second Revision)	Identical
ISO 5832-5, Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy	IS/ISO 5832 (Part 5) , Implants for Surgery — Metallic Materials Part 5 Wrought Cobalt-Chromium-Tungsten Nickel Alloy	Identical
ISO 5832-6, Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	IS 18261 (Part 6) , Implants for Surgery — Metallic Materials Part 6 Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy (First Revision)	Identical
ISO 5832-7, Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy	IS/ISO 5832-7 , Implants for Surgery — Metallic Materials Part 7 Forgeable and Cold-Formed Cobalt Chromium-Nickel Molybdenum-Iron Alloy	Identical
ISO 14630:2012, Non-active surgical implants — General requirements	IS 18076 : 2023, Non-active Surgical Implants — General Requirements (ISO 14630 : 2012, MOD)	Identical
ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IS/ISO 15223-(Part 1) , Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part	Identical

1 General Requirements
(Second Revision)

ISO 17664-1, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	IS/ISO 17664 , Processing of Health Care Products — Information to be provided by the Medical Device Manufacturer for the Processing of Medical Devices	Identical

This standard also makes a reference to the BIS Certification Marking of the product Details of which is given in National Annex A.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 9713: 2022 kindly contact:

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SCOPE

This document establishes the characteristics of self-closing aneurysm clips intended for permanent intracranial implantation and specifies requirements for their marking, packaging, and sterilization for labelling and accompanying documentation. In addition, it gives a method for the measurement of closing force.

This document is not applicable to malleable clips, or clips intended to be used during the course of surgery and removed before wound closure (temporary clips).

NOTE In this document when not otherwise established, the term “implant” refers to the self-closing intracranial aneurysm clips.