

**BUREAU OF INDIAN STANDARDS**

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**भारतीय मानक मसौदा**

**न्यूरोसर्जिकल प्रत्यारोपण - बाँझ, एकल-उपयोग हाइड्रोसिफलस शंट**

*(पहला पुनरीक्षण)*

(ISO 7197:2024)

***Draft Indian Standard***

**Neurosurgical Implants — Sterile, Single-Use Hydrocephalus Shunts**

*(First Revision)*

(ISO 7197:2024)

**[ICS 11.040.40]**

Neurosurgery Instruments Implants and  
Accessories Sectional Committee, MHD 07

Last Date for Comments: **20 Feb 2025**

**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:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- 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:

<i>International Standard</i>	<i>Corresponding Standard</i>	<i>Degree of Equivalence</i>
ISO/TR 14283 : 2018, Implants for Surgery - Essential Principles of Safety and Performance	IS/ISO/TR 14283 : 2018, Implants for Surgery - Essential Principles of Safety and Performance	Identical
ISO 14630: 2012, Non-active surgical implants - General requirements	IS 18076 : 2023, Non-active surgical implants - General requirements	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.

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**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 7197:2024 or kindly contact:

**Head (MHD)**  
**Bureau of Indian Standards**  
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**9, Bahadur Shah Zafar Marg**  
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**Scope**

This document specifies the performance requirements for sterile, single-use non-active hydrocephalus shunts. This includes not only the valve, but also additional components such as tubes and reservoirs.

This document does not provide any recommendations on which type of valve is most suitable for any specific context of use.

This document specifies the mechanical and technical requirements to manufacture shunts and the technical information of the valve to be supplied by the manufacturer.

This document does not apply to active implants for the treatment of hydrocephalus.