*भारतीय मानक*

***प्रकाशिकी और फोटोनिक्स* —**

***मेडिकल एंडोस्कोप और एंडोथेरेपी उपकरण* —**

***भाग* 8: *कैप्सूल एंडोस्कोप के लिए विशेष आवश्यकताएँ***

*Indian Standard*

**Optics and photonics —**

**Medical endoscopes and endotherapy devices —**

**Part 8: Particular requirements for capsule endoscope**

**ICS 11.040.55**

**NATIONAL FOREWORD**

This Indian standard (Part 6) is an identical adoption of ISO 8600-8:2021 ‘Endoscopes — Medical endoscopes and endotherapy devices — Part 8: Particular requirements for capsule endoscopes, issued by the International Organization for Standardization, was adopted by Bureau of Indian Standards on the recommendation of Surgical Instruments Sectional Committee MHD 01 and approval of the Medical Equipment and Hospital Planning Division Council.

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

1. Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’.
2. 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 standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

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| *International Standard* | *Indian Standard* | *Degree of Equivalence* |
| ISO 8600-1:2015, Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements | IS 15732 (Part 1): 2018  ISO 8600-1: 2015  Endoscopes - Medical Endoscopes and Endotherapy Devices Part 1 General Requirements (*First Revision*) | Identical |
| ISO 8600-4, Endoscopes — Medical endoscopes and endotherapy devices — Part 4: Determination of maximum width of insertion portion | IS 15732 (Part 4): 2021  ISO 8600-4:2014  Endoscopes - Medical endoscopes and endotherapy devices- Part 4: Determination of maximum width of insertion portion (First Revision) | Identical |
| IEC 60601-1-2, Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests | IS 13450 (Part 1/Sec 2): 2018  IEC 60601-1-2: 2014  Medical electrical equipment: Part 1 general requirements for the basic safety and essential performance: Sec 2 collateral standard: electromagnetic disturbances - Requirements and tests (First Revision) | Identical |

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with **IS 2: 2022** ‘Rules for rounding off numerical values (*Second Revision*)’.