

केन्द्रीय मुहर विभाग - III

हमारा संदर्भ- केन्द्रीय मुहर विभाग-3/16: IS 15354

विषय: अनुपालन हेतु गाइडलाइन

सभी शाखा कार्यालय से आग्रह है कि गाइडलाइन का अनुपालन तत्काल प्रभाव से सुनिश्चित करें।

(औरोस्मिता कबिराज)
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सभी क्षेत्रीय/शाखा कार्यालय
आई टी एस विभाग — बीआईएस इंटरनेट पर अपलोड करने हेतू

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-3/16: IS 15354

31 Jan 2019

Subject: Guidelines for implementation of Revised Standards IS 15354 (Part 1): 2018/ ISO 11193-1: 2008 and IS 15354 (Part 2): 2018/ ISO 11193-2: 2006 superseding IS 15354: 2003/ ISO 11193: 1994 - Single-Use Rubber Examination Gloves.

This has reference to the subject mentioned above.

BOs may kindly ensure implementation of the guidelines with immediate effect.

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Central Marks Department-III

Ref: CMD-III/16: IS 15354

31 Jan 2019

Subject: Guidelines for Implementation of Revised Standards IS 15354 (Part 1): 2018/ ISO 11193-1: 2008 and IS 15354 (Part 2): 2018/ ISO 11193-2: 2006 superseding IS 15354: 2003/ ISO 11193: 1994 - Single-Use Rubber Examination Gloves.

1. IS 15354 : 2003 has been revised and published in the following two parts:
 - i. **IS 15354 (Part 1): 2018/ ISO 11193-1: 2008**- Single-Use Medical Examination Gloves Part 1 Specification for Gloves Made from Rubber Latex or Rubber Solution
 - ii. **IS 15354 (Part 2): 2018/ ISO 11193-2: 2006** - Single-Use Medical Examination Gloves Part 2 Specification for Gloves Made from Poly Vinyl Chloride.
2. The last date for implementation of the revised Standards is **19 March 2019** after which the old Standard IS 15354: 2003/ ISO 11193: 1994 shall stand withdrawn.
3. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the revised Standard.
4. As IS 15354: 2003/ ISO 11193: 1994 covers gloves made from compounded natural or synthetic latex or compounded rubber solution, the same varieties would now be covered under IS 15354 (Part 1): 2018/ ISO 11193-1: 2008. Thus the significant changes between IS 15354: 2003 and IS 15354 (Part 1): 2018 along with the relevant Clause nos. of the new ISS are listed below for the purpose of general guidance. Licensees/ Applicants shall ensure that the product conforms to all the requirements, as applicable, as per the revised Standard.

Classification of gloves based on type and finish – Cl 3

Materials for manufacture have been specified – Cl 4

Thickness at textured area has been specified – Cl 6.1

Thickness of cuff termination has been specified – Cl 6.1

Size code added – Table 2

Max. thickness at approx. centre of palm has been specified – Table 2

Modification in test procedure for watertightness test – Cl 6.2

Tensile properties to be measured as Min. force at break (in N) instead of mi. tensile strength (in MPa) – Table 3

Marking requirements modified – Cl 8

5. Consequent upon the issuance of the revised Standard, existing STI has been revised as Doc: SIT/ IS 15354 (Part 1)/ 1 Jan 2019.

6. The guidelines for implementation of the revised Standard is given below:

A. Licensees:

- (i) All Licensees shall implement the revised Standard by **19 March 2019**. BOs shall ensure that no Licences are under operation as per the old Standard after **19 March 2019**.
- (ii) Licensees shall submit evidence of conformity to the additional/modified requirements through In-house/Independent Test Reports or Test Certificates, as applicable. Verification of additional facilities, if any, may be done during the next visit.
- (iii) If the Licensee fails to complete all actions by **19 March 2019** it shall be dealt with as per the prevailing guidelines.

B. Applications for Grant of Licence:

- (i) Existing Applications where Sample has been submitted in the Laboratory/Test Report has been issued by the Laboratory may be processed as per the old Standard. However, if the Applicant is desirous of considering the Application as per the revised Standard, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking shall from such Applicants also be obtained that in new test requirements, Licence will not be granted by BIS as per the old version.
- (ii) Applications which are recorded henceforth may be processed as per the old Standard or the revised Standard. Processing of Applications as per the old Standard shall be permitted only upto **19 March 2019** and for such cases Applicant shall give a declaration that they will implement the revised Standard by **19 March 2019**.
- (iii) Beyond **19 March 2019** no Licence shall be granted as per the old Standard.

C. Change in Scope of Licence:

- (i) For change in scope of licence, the relevant provisions as given above for Applicants shall apply.
- (ii) However, processing of such applications for change in scope of licence as per the old Standard shall be permitted only upto the date of implementation of the revised Standard or upto **19 March 2019** whichever is earlier.

7. The above guidelines come into force with immediate effect.

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