

केन्द्रीयमुहरविभाग-2

संदर्भ -: केमूवी-2/16:9473

09 12 2020

विषय:IS 9473:2002 के amendment no. 1 के अनुपालन के दिशा निर्देश

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशा निर्देश अनुपालन हेतु संलग्न है।

सभी क्षेत्रीय/शाखा कार्यालयों से अनुरोध है की दिशा निर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

आदित्य दास
वैज्ञानिकD

प्रमुख (केमूवी 2)

सभी क्षेत्रीय/शाखा कार्यालय/प्रयोगशालाएँ/CHD/LPPD

CENTRAL MARKS DEPARTMENT-2

OurRef:CMD-2/16:9473

09 12 2020

Subject: Guidelines for implementation of amendment no. 1 to IS 9473:2002

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

All ROs/BOs are requested to ensure the implementation of the above Guidelines with immediate effect.

(Aditya Das)
Scientist D

Head (CMD-2)

All ROs/BOs/Labs/CHD/LPPD

CENTRAL MARKS DEPARTMENT-2

OurRef:CMD-2/16:9473

Date: 09 12 2020

**Subject: Guidelines for implementation of Amendment no. 1 to IS 9473:2002 –
(Respiratory protective devices - Filtering half masks to protect against
particles - Specification)**

1. Amendment no. 1 to IS 9473:2002 has been published. The amendment shall be implemented with effect from **7 Sept 2021**.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above amendment **within a week of issuance of these guidelines**.
3. The significant changes in the standard through this amendment as listed in the Table are given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the amendment.

Clause	Change
5.4.2, A-4	Test method for penetration of filter material test has been changed (Testing of short-term penetration and full exposure penetration shall be done in accordance with IS 17274 (Part 3) at test aerosol flow rate of 95 l/min)
7.6	Instructions for use and discarding of masks have been modified. It has been specified that The manufacturer shall also provide detailed procedure for disposal of masks as per Solid Waste Management Rules, 2016 notified by Ministry of Environment, Forest and Climate Change.
8.3, Table 4	Summary of tests has been modified (as per Table 4). It has also been specified that wherever applicable (As indicated in table 4), equivalent automated instruments validated against the corresponding test methods prescribed in Annex A may be used. For total inward leakage, even if an automated instrument is used, the test subject shall follow the exercises prescribed in A-3.
A-8	Modifications have been made to method of test for breathing resistance by specifying different test samples, fixtures, etc. for valved and valve-less filtering half masks and changing the method of test for exhalation resistance.

4. The existing product manual has been revised to incorporate the amendment and it is being circulated separately through BIS website.
5. The guidelines for implementation of the amendment is given below:

A. LICENSEES:

- (i) All Licensees shall implement the amendment by **7 Sept 2021**. BOs shall ensure that no Licences are under operation as per IS 9473:2002 without the amendment after **7 Sept 2021**.
- (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 implementation of the amendment, wherever required, may be done during the next visit.

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 without consideration of the amendment. However, if the Applicant is desirous of considering the amendment, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking shall also be obtained from such Applicants that if the sample fails while considering the provisions of the amendment, Licence will not be granted as per the old version.
- (ii) Applications which are recorded henceforth may be processed with or without consideration of the amendment. Processing of Applications without consideration of the amendment shall be permitted only upto **6 Sept 2021** and for such cases Applicant shall give a declaration that they will implement the amendment by **7 Sept 2021**.
- (iii) Beyond **7 Sept 2021** no Licence shall be granted without consideration of the amendment.

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 without consideration of the amendment shall be permitted only up to the date of implementation of the amendment by the licensee or upto **7 Sept 2021** whichever is earlier.

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

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Head (CMD-2)
DDG (Certification)