

केंद्रीय मुहर विभाग-2

संदर्भ : कें.मु.वि-2/16:9473

06 05 2020

विषय: IS 9473:2002 Class FFP2 के अनुसार Respiratory Protective Devices - Filter Half Masks to Protect against particles के प्रमाणीकरण के लिए अतिरिक्त उत्पाद विशिष्ट दिशानिर्देश

कृपया कार्यान्वयन के लिए उपरोक्त विषय पर संलग्न अनुमोदित दिशानिर्देश देखें।

(आदित्य दास)
वैज्ञानिक - डी

प्रमुख, (कें.मु.वि.-2)

उपमहानिदेशक (प्रमाणन)

क्षेत्रीय/शाखा कार्यालयों को intranet माध्यम से परिचालित

प्रतिलिपि: ITS - इंटरनेट पर अपलोड करने के लिए

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:9473

06 05 2020

Subject: Additional Product Specific Guidelines for certification of Respiratory Protective Devices – Filter Half Masks to Protect against particles of Class FFP2 as per IS 9473:2002

Please find attached approved guidelines on the above subject for implementation.

Aditya Das
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Head (CMD 2)

DDG (Certification)

Circulated to: All ROs/BOs through BIS intranet

Copy to: ITS for hosting on Intranet

CENTRAL MARKS DEPARTMENT-2

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Subject: Additional Product Specific Guidelines for certification of Respiratory Protective Devices – Filter Half Masks to Protect against particles of Class FFP2 as per IS 9473:2002

1. This has reference to the above.
2. At present, since there are no BIS Labs or BIS recognized/empanelled labs equipped for testing as per IS 9473:2002, the certification of this product is being done on factory testing basis i.e. presently licences are being granted only to those manufacturers who have complete in-house testing facilities.
3. Since Class FFP2 Masks (or N95 masks) is an essential PPE item in this pandemic situation, and the existing production capacity of the FFP2 masks with ISI mark is not adequate within the country, it has been decided to allow the grant of licence even to the manufacturers of FFP2 masks who do not have in house testing facilities.
4. Following guidelines are issued in this regard:
 - i) Licence shall be granted by BIS under Scheme-I as per existing procedure for a period of one year.
 - ii) During the factory visit for considering grant of licence, factory testing should be conducted in the applicant's factory for only those requirements for which testing facilities are available with the applicant. For the remaining requirements, sufficient sample quantity shall be tested in the in-house lab of BIS licensee for Class FFP2 masks as per IS 9473:2002, which will be witnessed by a BIS Certification Officer from the BIS Branch Office having jurisdiction over the BIS licensee in whose lab the sample is being tested.
 - iii) The BIS licensee in whose lab the samples of the applicant/licensee without in-house testing facilities are to be sent shall be decided by the BIS Branch Office having jurisdiction over the applicant/licensee whose samples are being sent.
 - iv) Grant of licence shall be considered based on the above test results.

- v) While granting licence, the following will be added in the conditions of the licence:
- a) The manufacturer has to establish all test facilities for testing masks as per IS 9473:2002 for the varieties in their scope of licence, implement the Scheme of Inspection and Testing as per IS 9473:2002 and confirm the same to BIS within 4 months of the date of grant of licence.
 - b) Till the time complete in-house test facilities are established, the manufacturer will get their product samples tested in the test facility available with BIS licensees (for Class FFP2 masks as per IS 9473:2002) or any BIS recognised labs (equipped with test facilities for IS 9473:2002) on weekly basis, as per the sampling parameters defined by BIS.
 - c) The manufacturer will use BIS Standard Mark on only those masks which are meant for supply to HLL Lifecare/Government of India till the time complete in-house test facilities are established by them and verified by BIS.
5. In case licensee fails to establish all test facilities for complete testing of masks as per IS 9473:2002 for the varieties in their scope of licence, implement the Scheme of Inspection and Testing as per IS 9473:2002 and confirm the same to BIS within 4 months of the date of grant of licence, the licence shall be placed under suspension; if licensee fails to complete the pending action within 90 days, the licence shall be processed for cancellation as per procedure.
6. In case licensee confirms establishment of test facilities and SIT within 4 months of grant of licence, the concerned BO shall depute a BIS Certification Officer for an immediate visit for verification of the same. If verification is satisfactory, normal operation of licence shall be allowed to continue and the additional conditions of licence mentioned in para 4 (v) shall be removed by issuing a suitable endorsement to the licence.
7. If the verification is unsatisfactory, the licensee shall be advised to complete the deficiencies within the last date of the 4 month period failing which the licence shall be placed under suspension.

8. These guidelines shall be in force till further orders.

9. All ROs/BOs are requested to follow these guidelines for certification of Class FFP2 Masks as per IS 9473:2002.

Aditya Das
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ROs/BOs