केंद्रीय मुहर विभाग-2

संदर्भ वि.मु.कें :-2/16:9473 15 05 2020

विषय: **IS 9473:2002 Class FFP2 के अनुसार Respiratory Protective Devices – Filter Half Masks to Protect against particles के लिए संशोधित Consolidated उत्पाद विशिष्ट दिशा निर्देश**

उपरोक्त विषय के संदर्भ में अनुमोदित संशोधित Consolidated उत्पाद विशिष्ट दिशा निर्देश अनुपालन हेतु संलग्न है।

(आदित्य दास)
वैज्ञानिक-डी

प्रमुख, (कें.मु.वि.-2)
उपमहानिदेशक(प्रमाणन)
क्षेत्रीय/शाखा कार्यालयों को intranet माध्यम से परिचालित

प्रतिलिपि: ITS - इंट्रानेट पर अपलोड करने के लिए

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:9473 15 05 2020

Subject: Modified Consolidated 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 modified guidelines on the above subject for implementation.

Aditya Das
Sc. D

Head (CMD 2)
DDG (Certification)
Circulated to: All ROs/BOsthrough BIS intranet

Copy to: ITS for hosting on Intranet

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:9473 15 05 2020

Subject: Modified Consolidated 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 is with reference to the **consolidated guidelines** for certification of Respiratory Protective Devices – Filter Half Masks to Protect against particles of Class FFP2 as per IS 9473:2002 issued on 11.05.2020.

2. As per the above guidelines, licences were to be granted on the condition that the manufacturers will establish the required in-house testing facilities within 4 months of being granted a licence.However, it was felt that given the high costs of setting up in-house testing facilities, it would be difficult for manufacturers, especially MSME units to set up test facilities in-house even after these 4 months, especially in the dire economic environment prevailing due to the COVID-19 pandemic. Accordingly, it has now been decided that that even after lapse of 4 months, BIS shall not insist that the units establish in-house testing facilities.

3. Further, as per the above guidelines, after grant of licence, the licensees were required to get samples tested weekly for all requirements of the Indian Standard in the lab of BIS licensee or in third party labs, till the time in-house test facilities have been established. It has now been decided to withdrawn this condition as well. Instead, the licensee shall be required to comply with the requirements of the modified Scheme of Inspection and Testing, circulated separately, in which the frequency of the daily (each batch/control unit) tests has been relaxed to weekly (every 7thcontrol unit) and subcontracting of all tests has been permitted.

4. Accordingly, the following modified consolidated guidelines are issued **in supersession of** the guidelines issued vide CMD-2's circular dated 11.05.2020:

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. The applicant sample is to be sent for testing **for all the requirements of the standard**, to a BIS licensee for Class FFP2 masks as per IS 9473:2002.

iii) The testing of sample at the factory of the BIS licensee shall 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.

iv) **The applicant shall bear the cost of sending the samples to the BIS licensee and also bear the testing charges (if any). The testing charges shall be paid directly by the applicant to the licensee in whose lab the samples are to be tested.**

v) The BIS licensee in whose lab the samples of the applicant without in-house testing facilities are to be sent shall be decided by the BIS Branch Office having jurisdiction over the applicant whose samples are being sent. **However, the BO (under whose jurisdiction the applicant falls) shall inform the sample dispatch details to CMD-2 as well as the BO under whose jurisdiction the lab is located.**

vi) Inspection charges for one day for the visit at the applicant's factory premises i.e. Rs 7000 (plus applicable taxes) shall be collected from the applicant. No charges shall be collected for the visit paid at the licensee's unit for witnessing the testing.

vii) While granting licence, the following will be added in the conditions of the licence:

a) The manufacturer shall use BIS Standard Mark on only those masks which are meant for supply to HLL Lifecare/Government of India for a period of 4 months from the date of grant of licence and till the period beyond that as specified by BIS.

viii) After grant of licence, the licensee shall be required to comply with the provisions of the modified Scheme of Inspection and Testing (SIT), which is being circulated separately.

ix) In all other respects, the certification shall be done as per the provisions of the BIS (Conformity Assessment) Regulations, 2018 and guidelines issued thereunder.

5. All ROs and BOs are directed to follow these guidelines for certification of Class FFP2 Masks as per IS 9473:2002 till further orders.

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