केंद्रीय मुहर विभाग-2

संदर्भ वि.मु.कें :-2/16:9473 11 05 2020

विषय:**IS 9473:2002 Class FFP2** के अनुसार **Respiratory Protective Devices - Filter Half Masks to Protect against particles** के प्रमाणीकरण के लिए **Consolidated** 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 - इंट्रानेट पर अपलोड करने के लिए

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:9473 11 05 2020

Subject: 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 guidelines on the above subject for implementation.

Aditya Das
Scientist. 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 11 05 2020

Subject: 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. Based on the deliberations with the Heads of Regional and Branch offices of BIS (ROs/BOs), **consolidated guidelines** for certification of Respiratory Protective Devices – Filter Half Masks to Protect against particles of Class FFP2 as per IS 9473:2002, are issued by incorporating new provisions, as given hereunder in the 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 issued on 06.05.2020: -

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. A specimen test report format which may be adopted is enclosed as **Appendix-I.**

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 licensee 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.

vii) 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 **shall send a sample quantity of 70 masks to any BIS licensee (for Class FFP2 masks as per IS 9473:2002) or any BIS recognised lab (equipped with test facilities for IS 9473:2002) on weekly basis for complete testing as per IS 9473:2002.**

c) The manufacturer shall ensure that the 70 masks shall be selected from each day's production in a week proportionate to the volume of production per day of the week e.g. if the manufacturer produces an equal quantity of FFP2 masks per day for 7 days a week, 10 masks of Class FFP2 shall be randomly selected from each day's production to make up the 70 masks for the sample.

d) The manufacturer shall inform both the BIS Branch Offices concerned, of the dispatch of samples and share a copy of the test reports.

e) The manufacturer shall 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.

viii) 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.

ix) 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 2 (v) shall be removed by issuing a suitable endorsement to the licence.

x) 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.

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

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

Aditya Das
Sc. D

HCMD-2
DDG (Certification)
ROs/BOs

APPENDIX 1

SPECIMEN Test Report Format

Details of Licensee in whose lab testing is being conducted.

Name of Licensee :
Licensee Number:
Address:
Scope of Licence: [Must include Class FFP2]

Details of the Sample:
Sample Code: [To be filled from test request]

Product : Respiratory Protective Devices- Filtering half mask to Protect again particles,
Class: FFP2 , with/without Exhalation Valves, Solid/Liquid, Designed/Not designed for Single Use only,
Indian Standard: IS 9473:2002 (No. of amendments considered: ….)
Batch No. & Date of Manufacturing: [To be filled from test request]

Date of start of testing:
Date of completion of Testing:

S No.	Test	Clause	IS Ref.	Specified Requirement	Observed values	Remarks
1	Material	5.1.1	9473	The face piece or Straps shall not suffer deformation after conditioning as per A-1		
2	Material	5.1.2	9473	The, mask shall not collapse after simulated wearing & temp conditioning as per A-1 and A-2		
4	Material	5.1.3	9473	Any material from the filter media released by air flow through the filter should not constitute a hazard/ nuisance to the wearer.		
5	Metal Parts	5.1.4	9473	Use of metal parts be restricted to minimum.		

6	Cleaning & Disinfection	5.2	9473	The materials used shall withstand the cleaning and disinfecting agents recommended by the manufacturer.		Not applicable for single use masks
7	Practical Performance test	5.3	9473	After the walking practical performance tests as per A-2, the test subjects were asked following question: a. Head harness comfort: b. Security of fastenings:, c. Field of vision (A-8 of IS 14746.) d. any other comments:		
8	Total Inward leakage	5.4.1	9473	When tested according to A-3, the filtering half masks fitted in accordance with the manufacturer's instruction, at least 46 out of 50 individual exercise results (that is, 10 subjects x 5 exercises) for the total inward leakage:	-	-
8a	-do-	5.4.1a	9473	total inward leakage shall not be greater 25% for FFP1, 11% for FFP2, 5% for FFP3		
8b	-do-	5.4.1.b	9473	At least 8 out of 10 individual wearer arithmetic means for the total inward leakage shall not be greater than 22% for FFP1, 8% for FFP2, 2% for FFP3.		
9	Penetration of Filter material	5.4.2	9473	The leakage shall not be greater than 6% for FFP2.		
10	Penetration of Filter Material (MS-3 Nos.)	5.4.2	9473	As per Table 1 The leakage shall not be greater than 6% (Sodium Chloride Test) and 2% (Paraffin Oil test) for FFP2.		
11	Compatibility with skin	5.5	9473	Material shall suitable & shall not cause itching/other nuisance to the user after coming in contact.		
12	Flammability	5.6	9473	When tested as per A-5, The mask shall		

				not continue to burn after removal of flame.		
13	Carbon Dioxide Content of the Inhalation Air	5.7	9473	When tested in accordance with A-6, the carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 percent (by volume).		
14	Head Harness comfort	5.8.1, 5.8.2	9473	After testing according to A-2, The test subjects were asked if the head harness was comfortable, held the mask firmly in place, was adjustable or self-adjustable and allowed the filtering half mask to be donned and removed easily		
15	During Leakage Test	5.8.2	9473	When tested according to A-2, A-3, was capable of maintaining total inward leakage requirements for the device when tested in accordance with A-2 and A-3.		
16	Field of Vision	5.9	9473	The field of vision shall be acceptable when determined so during the practical performance testsin accordance with A-2		
15	Inhalation Valve	5.10.1	9473	filtering half mask may have one or more inhalation valve(s).		
16	Exhalation valve	5.10.2.1	9473	filtering half mask may have one or more exhalation valve(s) and, if fitted, shall function correctly in all orientations, when tested according to A-3.		
	-do-	5.10.2.2	9473	If an exhalation valve is provided, it shall be protected against dirt and mechanical damage, and shall be shrouded or shall include any other device that may be necessary for the filtering half mask to comply with A-3.		
15	Exh. Valve flow	5.10.2.3	9473	After 300 1pm exposure of 30s the exh.		

<table>
<tr><td></td><td></td><td></td><td></td><td>Valve shall work satisfactorily.</td><td></td><td></td></tr>
<tr><td>16.a</td><td>Exh. Valve Tensile Force</td><td>5.10.2.4</td><td>9473</td><td>The Exh. Valve shall withstand axially 10N tensile force without damage.</td><td></td><td></td></tr>
<tr><td>16.b</td><td>Exh. Valve Tensile Force</td><td>5.10.2.4</td><td>9473</td><td>The Exh. Valve shall with stood 10N tensile force without damage.</td><td></td><td></td></tr>
<tr><td>17</td><td>Breathing Resistance Test</td><td>5.11</td><td>9473</td><td>The resistance shall not exceed the following for FFP 2 when tested as per A-8
<table>
<tr><td>Mask</td><td>Max</td></tr>
<tr><td>Inh. 301pm</td><td>0.7</td></tr>
<tr><td>Inh. 951pm</td><td>2.4</td></tr>
<tr><td>Inh. 1601pm</td><td>3</td></tr>
</table></td><td></td><td></td></tr>
<tr><td>18</td><td>Breathing resistance after Clogging for valved filtering half masks</td><td>5.12.2.1</td><td>9473</td><td>A. The inhalation resistance shall not be greater than 4 mbar for FFP 1 and 5 mbar for FFP2 when tested for breathing resistance at 95 l/min, in accordance with A-8 after the treatment.

B. The exhalation resistance shall not be greater than 3 mbar at 160 l/rein continuous flow.</td><td></td><td></td></tr>
<tr><td>19</td><td>Breathing resistance after Clogging for valveless filtering half masks</td><td>5.12.2.1</td><td>9473</td><td>The inhalation and exhalation resistances shall not be greater than 3 mbar for FFP1 and 4 mbar for FFP2,
when tested for breathing resistance at 95 l/min continuous flow, in accordance with A-8.</td><td></td><td></td></tr>
<tr><td>20</td><td>Filter Penetration</td><td>5.12.3</td><td></td><td>All filtering half masks (valved and valveless) which
meet the clogging requirement (see 5.12.1 and 5.12.2)
shall also comply with the penetration requirements</td><td></td><td></td></tr>
</table>

				given in 5.4.2 after the treatment		
18	Demountable Parts, visual inspection & user instructions	5.13,	9473	All demountable parts shall be readily connected & secured when tested as per A-11		

Remarks: The sample was found to be conforming/non conforming to the requirements of IS 9473:2002

Tested by: (Signature of QC In charge)

Name:

Designation :

For (Name of the Licensee)

Witnessed By: (Signature of BIS CO)

Name:

Designation:

Date:

Place: