भारतीय मानक ब्यूरो
Bureau of Indian Standards
The National Standards Body of India

Address: Delhi Branch Office - I-Manak Bhavan,
9 Bahadur Shah Zafar Marg, Delhi-110002
Phone: 011-23230131, 23233375
Fax: 01123234062
E-Mail: dlbo1@bis.gov.in
Web: www.bis.org.in, www.manakonline.in

Our Ref :DLBO-I/CM/L 8100098110 **14/09/2020**

Subject: Grant of BIS Certification Marks Licence No. 8100098110 as per IS 9473:2002.

M/s.Duraplus Healthcare
B-83, Naraina Industrial Area, Phase - 2,
New Delhi – 110028.

Dear Madams(s)/Sir,

With reference to your application, we are pleased to inform you that the Certification Marks Licence has been granted to you to use the Standard Mark in respect of the followings:

Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles

Product:-

Grade/Class/Type/Variety
Class FFP2, Sub Class- S (Solid), Type : Without exhalation valve, Single use, Without resistance to clogging

1. The licence is granted on the explicit condition that you will mark substantial production which conforms to the Indian Standards.

2.The number assigned to this licence is CM/L- **8100098110** which has been made operative from **10/09/2020** and is valid upto **09/09/2021**. The licence number should invariably be referred to in your future correspondence.

According to sub-regulation (1) &(3) of Paragraph 5 of scheme I of Schedule II under Bureau of Indian Standards (Conformity of Assessment) Regulation, 2018, the annual licence fee of Rs. 2000.00 and the marking fee for use of standard mark as per Annexure-I of Scheme I of BIS(Conformity assessment) Regulation 2018 is payable by you with effect from **09/09/2020** for the period of validity of the licence licence in advance.

3. Minimum marking fee stipulated in Annexure -I of scheme I of BIS (Conformity Assessment) Regulation 2018 is payable by you regardless of the whether you actually mark your product or not with the Standard Mark.**Our Receipt No. 0081PC2020000785** dated **09/09/2020** for the licence fee and the minimum marking fee for the first operative period is already enclosed separately.

4. This advance minimum marking fee will be carried over to the next year on every renewal. The actual marking fee calculated on the unit rate on the production marked or the minimum marking fee, whichever is higher shall be payable by you at the time of renewal.

5.With a view to streamlining the reporting of quantity marked, calculation and collection of marking fee on the unit rate basis, fees will be calculated on the production marked during the first nine months of operation of the licence at the time of first renewal, and on the production marked during twelve months comprising the last three months of the previous operative year and the first nine months of the current operative year, at the time of the second and subsequent renewals. In case the licence expires, the entire production marked till the expiry date shall be taken into account for calculating the marking fee payable.

6.The Scheme of Inspection and Testing as specified by BIS will have to be implemented by your organization strictly and completely. This supervision of the operation of the Scheme shall be done by a person responsible for the quality control function in your organization. Kindly inform us the name and designation of the person who will be held responsible for the operation and maintenance of the Scheme. Any future change in this respect will have to be communicated by you to us as and when these take place. **You are requested to follow the guidelines of CMD-2/16:9473 dated 15/05/2020 as mentioned at Clause No. vii)a) and viii). (copy enclosed)**

7.We are enclosing a sheet giving the preferred dimensions of the Standard Mark to enable you to prepare the designs of the Standard Mark for marking the above product Photographic reduction in any size is permissible. This will ensure the relative proportions of the different dimensions maintained. Preferred dimensions be used as far as possible.

8.On commencement of marking of your product for which you are licensed, you may advertise your product with Standard Mark in various media only during the validity of your licence. The use of Standard Mark on letterheads and publicity literature will be permitted only on receipt of your assurance that in the event of cancellation or lapsing of your licence, the Standard Mark on your letterheads, publicity literatures etc. will be destroyed/obliterated.

9.This licence is granted for your factory situated **at B-83, Naraina Industrial Area, Phase - 2, New Delhi – 110028.** Privileges under the licence shall not be exercised by any other firm company/factory etc. This licence is not transferable in the event of shifting the manufacturing and testing equipment from the licensed premises to some other place, use of Standard Mark shall be stopped till the new premises are inspected and found to be satisfactory by us in respect of manufacturing and testing facilities available there and the address of the new premises is endorsed in the licence.

Thanking You,

18/09/2020

S K Verma
Scientist E & Head (DLBO-I)

Annexure-II
(Refer sub-paragraph (1) of paragraph 6 of Scheme - I)

STANDARD MARK

DESIGN OF MONOGRAM FOR STANDARD MARK

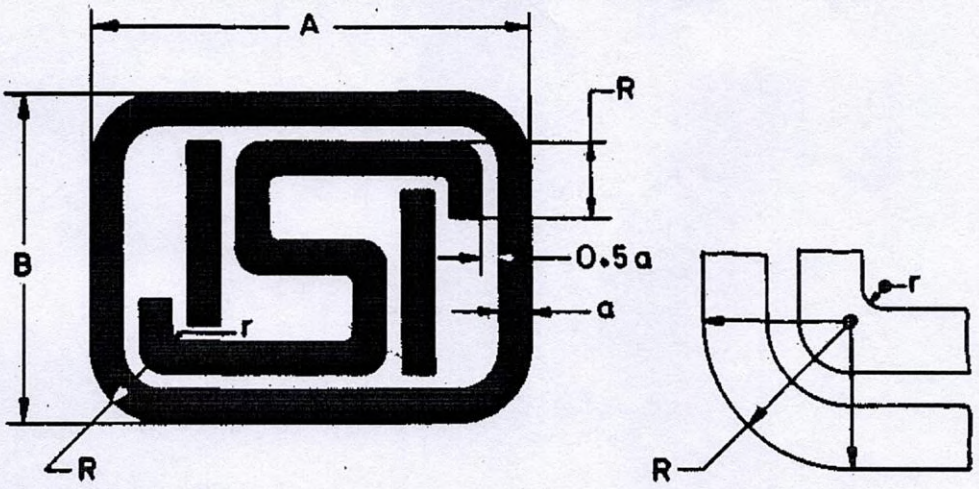

Figure 1 MONOGRAM FOR STANDARD MARK

The monogram of the Standard Mark consists of the pictorial representation, drawn in the exact style as indicated in Figure 1 and in relative proportions as given in Table 1.

Table 1 Preferred Dimensions of Monogram
All dimensions in millimeters

A	B	a	R	r	SIZE OF LETTERS
2.5	1.9	0.2	0.4	-	1.0 mm
5	3.8	0.4	0.8	0.1	1.0 mm
10	7.5	0.7	1.7	0.2	2.0 mm
20	15	1.5	3.3	0.5	3.0 mm
40	30	2.9	6.7	1.0	4.0 mm
80	60	5.9	13.4	1.9	6.0 mm
160	120	11.7	26.7	3.8	10.0 mm
320	240	23.4	53.4	7.6	16.0 mm

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.

Aditya Das
Sc. D

HCMD-2
DDG (Certification)
ROs/BOs