

## केंद्रीय मुहर विभाग-2

संदर्भ वि.मु.के :-2/16:16289

19 05 2020

**विषय: IS 16289:2014 के अनुसार Surgical Face Masks के लिए उत्पाद विशिष्ट दिशा निर्देश**

उपरोक्त विषय के संदर्भ में अनुमोदित 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 - इंटरनेट पर अपलोड करने के लिए

## CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:16289

19 05 2020

**Subject: Product Specific Guidelines for certification of Surgical Face Masks as per IS 16289:2014**

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

Aditya Das

Sc. D

**Head (CMD 2)**

**DDG (Certification)**

**Circulated to: All ROs/BOs through BIS intranet**

**Copy to: ITS for hosting on Intranet**

## CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:16289

19 05 2020

**Subject: Product Specific Guidelines for certification of Surgical Face Masks as per IS 16289:2014**

1. This is with reference to Surgical Face Masks as per IS 16289:2014 which is under voluntary certification on factory-testing basis. Presently, since there are no BIS labs or BIS recognized labs for this product, licences are being granted to only those manufacturers who have complete in-house testing facilities.
2. However, in order to ensure supply of adequate numbers of quality surgical face masks to meet their demand during the ongoing COVID-19 pandemic, it has been decided to relax the conditions of grant of licence for the above product to allow grant of licence to those manufacturers who do not have in-house testing facilities, based on testing of their product in the in-house labs of BIS licensees or third party labs.
3. Accordingly, the following guidelines are issued for certification of surgical face masks as per IS 16289:2014:
  - 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 IS 16289:2014 or to a BIS lab or BIS recognized/empanelled lab with test facilities as per IS 16289:2014.
  - iii) If the testing of sample is done at the factory of the BIS licensee, it 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 or the BIS lab or BIS recognized/empanelled lab and also bear the testing charges (if any). The testing charges shall be paid directly by the applicant to the licensee in whose lab or the lab where 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.

4. The present Scheme of Inspection and Testing (SIT) does not permit subcontracting of tests. However, in accordance with the above, a modified SIT is being issued separately in which the frequency of the daily (per control unit) tests is being relaxed to per week (i.e. every 7<sup>th</sup> control unit) and subcontracting is being permitted for all tests. After grant of licence, the licensee shall be required to comply with the provisions of the modified Scheme of Inspection and Testing (SIT).
5. In all other respects, the certification shall be done as per the provisions of the BIS (Conformity Assessment) Regulations, 2018 and guidelines issued thereunder.
6. All ROs and BOs are advised to follow these guidelines for certification of surgical face masks as per IS 16289 till further orders.

Aditya Das  
Sc. D

**HCMD-2**  
**DDG (Certification)**  
**ROs/BOs**