

CENTRAL MARKS DEPARTMENT III

Our Ref: CMD III/16: 12227

20 April 2020

Subject: Guidelines for implementation of Revised IS 12227:2020 [Sterile Single-Use Syringes, With or Without Needle, for Insulin]

1. IS 12227:2002 has been revised as IS 12227:2020 and has been published. The last date for implementation of the revised Standard is 08 Nov 2020 after which the old Standard shall stand withdrawn.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the revised Standard **within a week of issuance of these guidelines**. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised Standard.
3. Consequent upon the issuance of the revised Standard, existing STI has been revised as Doc: SIT/12227/1 April 2020.
4. The guidelines for implementation of the revised Standard is given below:

A. LICENSEES:

- (i) All Licensees shall implement the revised Standard by 08 Nov 2020. BOs shall ensure that no Licences are under operation as per the old Standard after 08 Nov 2020. **The status of implementation of the revised Standard shall be confirmed by Head (BO) to CMD-III within two weeks of the last date of concurrent running.**
- (ii) Licensees shall submit evidence of conformity to the additional/modified requirements through In-house/Independent Test Reports or Test Certificates, as applicable. Verification of implementation of the revised Standard, wherever required, may be done during the next visit **which may normally be completed within three months of the last date of concurrent running.**
- (iii) If the Licensee fails to complete all actions by 08 Nov 2020 it shall be dealt with as per the prevailing guidelines.

B. APPLICATIONS FOR GRANT OF LICENCE:

- (i) Existing Applications where Sample has been submitted in the Laboratory/Test Report has been issued by the Laboratory may be processed as per the old Standard. However, if the Applicant is desirous of considering the Application as per the revised Standard, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking shall also be obtained from such Applicants that if the sample fails in new test requirements, Licence will not be granted by BIS as per the old version.
- (ii) Applications which are recorded henceforth may be processed as per the old Standard or the revised Standard. Processing of Applications as per the old Standard shall be permitted

only upto 08 Nov 2020 and for such cases Applicant shall give a declaration that they will implement the revised Standard by 08 Nov 2020.

(iii) Beyond 08 Nov 2020 no Licence shall be granted as per the old Standard.

C. CHANGE IN SCOPE OF LICENCE:

- (i) For change in scope of licence, the relevant provisions as given above for Applicants shall apply.
 - (ii) However, processing of such applications for change in scope of licence as per the old Standard shall be permitted only upto the date of implementation of the revised Standard or upto 08 Nov 2020 whichever is earlier.
5. The above guidelines come into force with immediate effect.

(Jagannath Majhi)
Sc-E

Head (CMD III)
DDG (Certification)