

**भारतीय मानक ब्यूरो
(केंद्रीय मुहर विभाग III)**

हमारा संदर्भ: सी एम डी - III/16 : IS 10258 (भाग 1)

12 Jan 2024

विषय : संशोधित आईएस 10258 (भाग 1) के अनुपालन हेतु गाइडलाइन

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्न है।

सभी क्षेत्रीय / शाखा कार्यालयों से अनुरोध है की दिशा निर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

(राहुल विश्वकर्मा)
वैज्ञानिक सी (सी एम डी-III)

प्रमुख (सी एम डी- III)
सभी क्षेत्रीय /शाखा कार्यालय

**BUREAU OF INDIAN STANDARDS
(Central Marks Department-III)**

Our Ref: CMD-III/16: IS 10258 (Part 1)

12 Jan 2024

Subject: Guidelines for implementation of **Revised IS 10258 (Part 1): 2023 - Sterile Hypodermic Syringes for Single Use Part 1 Syringes for Manual Use**

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

All ROs/BOs are requested to ensure the implementation of the above Guidelines with immediate effect

(Rahul Vishwakarma)
Scientist C (CMD-III)

Head (CMD-III)
Circulated to: All ROs/BOs

CENTRAL MARKS DEPARTMENT – III

Our Ref: CMD III/16: IS 10258 (Part 1)

12 Jan 2024

Subject: Guidelines for implementation of Revised IS 10258 (Part 1): 2022/ISO 7886-1:2017 - Sterile Hypodermic Syringes for Single Use Part 1 Syringes for Manual Use

1. IS 10258: 2002 has been revised to IS 10258 (Part 1): 2022/ISO 7886-1:2017 - Sterile Hypodermic Syringes for Single Use Part 1 Syringes for Manual Use. The last date of concurrent running of the both old and new version of Indian Standard is 23 March 2024.
2. The significant changes in the revised Standard as listed in the Table is given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised Standard:

Cl. No. / Page No.	Changes
Cl. 4 Page 4	Drawing to illustrate the component of the syringe have been clarified
Cl. 5 Page 5	General Requirements (design inputs for manufacturers) have been added
Cl. 13.3 Cl. 13.4 Page 10	Test methods like 'Force to operate the piston', 'Fit of plunger stopper/plunger in barrel' have been revised
Cl.14 Page 11	Labelling and Packaging requirements have been modified
Annex – E Page 21	Test method for the determination of forces required to operate the piston has been revised
Annex F Page 25	Test method for the quantity of silicone have been added

3. Consequent upon issuance of the revised Standard, the Product Manual has been revised as Product Manual Doc: **PM/ IS 10258 (Part 1)/ 3/ December 2023** and is being circulated separately through BIS website.
4. The guidelines for implementation of the revised Standard is given below:

A. LICENSEES

- i. Licensee shall submit the test report of modified requirements either through in-house test report / test report from BIS approved third party laboratory of the product in order to establish the conformity. Firm further has to submit the type of lubricant it intends to use alongwith additional / modified test facilities as per the revised Indian Standards.
- ii. Any difficulty in implementation shall be brought to the notice of CMD III within 30 days of issuance of these guidelines. BO shall ensure that no Licences are under operation as per old Standard after 23 March 2024. 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.

- iii. Verification of implementation of the Revised IS 10258 (Part 1): 2022 shall be done through a surveillance visit, which shall be completed within one months from the last date of implementation.
- iv. If the Licensee fails to complete all actions by 23 March 2024, 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 without consideration of the revised Standard. However, if the Applicant desires to get the licence with 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 while considering the provisions of the revised Standard, Licence will not be granted as per the old version.
- ii. Applications which are recorded henceforth may be processed as per old Standard. Processing of Applications as per old Standard shall be permitted only up to 04 April 2024 and for such cases Applicant shall give a declaration that they will implement the revised Standard by 23 March 2024.
- iii. After 23 March 2024, no Licence shall be granted without consideration of the revised 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 up to the date of implementation of the revised Standard or up to 23 March 2024 whichever is earlier.

5. The above guidelines come into force with immediate effect.

Rahul Vishwakarma
Scientist C

Head (CMD III)
DDG (Certification)