भारतीय मानक ब्यूरो
केन्द्रीय मुहर विभाग – III

संदर्भ – के. मु. वि.-3/16: आई एस 13422 / आईएसओ 10282 **18 मार्च 2025**

विषय: पुनरीक्षित आई एस 13422: 2024 / आईएसओ 10282: 2023 के अनुपालन के लिए दिशानिर्देश

इसमें ऊपर उल्लिखित विषय का संदर्भ है

सभी शाखा कार्यालयों से आग्रह है कि गाइडलाईन का अनुपालन तत्काल प्रभाव से सुनिश्चित करें

(राहुल विश्वकर्मा)
वैज्ञानिक 'डी'/संयुक्त निदेशक (के मु वि III)

प्रमुख (के मु वि III)
सभी क्षेत्रीय/शाखा कार्यालय

BUREAU OF INDIAN STANDARDS
CENTRAL MARKS DEPARTMENT-III

Our Ref: **CMD-3/16: IS 13422 / ISO 10282** **18 March 2025**

Subject: Guidelines for Implementation of revised IS 13422: 2024 / ISO 10282: 2023

This has reference to the subject mentioned above.

BOs may kindly ensure the implementation of the guidelines with immediate effect.

(Rahul Vishwakarma)
Scientist - D/Joint Director (CMD III)

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

CENTRAL MARKS DEPARTMENT – III

Our Ref: CMD III/16: IS 13422 18 March 2025

Subject: Guidelines for implementation of Revision of IS 13422: 2024 / ISO 10282: 2023 – Single-Use Sterile Rubber Surgical Gloves — Specification

1. IS 13422: 1992 – Single-Use Sterile Rubber Surgical Gloves — Specification has been revised IS 13422: 2024 / ISO 10282: 2023 and the last date of concurrent running of the Standard with and without Revision was 29 Jan 2025. However, the last date of concurrent running of the Standard with and without Revision has been extended till 29 Jul 2025.

2. The standard was first published in 1992 as IS 13422 'Disposable surgical rubber gloves — Specification'. This revision of this standard has been brought out to align it with the latest version of ISO 10282: 2023. The significant changes brought through this Revision is tabled below:

Clause No. and Clause	***Changes***		***Action required***
2 Normative references	Normative references have been updated		No action needed
3 Terms and definitions	Terms and definitions have been specified		No action required
4 Classifications	New Gloves classification based on Design and Finish which were not specified in the earlier version have been included. The classification was earlier based on only Type of Gloves (i.e material of construction of gloves). However, the revised standard has added new materials for construction of gloves of Type - II.		Firm to declare the revised scope based on the classification as per revised standard. Scope of the licence is to be restricted based on the declaration made and already covered under the scope of licence.
	Based on Material	Type – I	No change
		Type – II	New raw materials added for construction of gloves. Firm shall submit the declaration of raw material it intends to use
	Based on Design	Gloves with straight fingers	Firm to submit the declaration 'Based on design', however, conformity of Gloves with fingers curved in the palmar direction is to be submitted either through In-house test report or test report issued from BIS Approved lab
		Gloves with fingers curved in the palmar direction	
	Based on Cuff Termination	Cut	Firm to submit the declaration
		Rolled rim	
	Based on Finish	Textured surface over part or the entire glove	Firm to submit the declaration w.r.t finish of gloves.Conformity of gloves having 'Powdered surface' and 'Powder-free surface' is to be submitted by the firm either
		Smooth surface	
		Powdered surface	
		Powder-free surface	

			through In-house test report or test report issued from BIS Approved lab
5.1 Materials	Materials New variety of raw materials are added for manufacturing Gloves Requirement of donning the gloves has been specified.		Firm to declare the raw material they intend to use for manufacturing gloves and submit the compliance of the same either through In-house test report or test report issued from BIS Approved lab. Firm has to submit the test report issued from BIS Approved lab for compliance of donning. Scope of the licence is to be modified as per the declaration of materials.
6 Sampling and selection of test pieces	Sampling and selection of test pieces Inspection levels and AQLs defined in Table 1		No action required
7 Requirements	Requirements		
7.1 Table 2 Dimensions	Dimensions New sizes (i.e. 5 and 9.5) have been added. Additionally, the requirement of length, width and thickness of existing sizes has been modified. Test method for measuring dimension has been added and defined in **Annex - A**		Firm to submit the conformity of the revised requirement of dimensions either through In-house test report or test report issued from BIS Approved lab. Firm to declare the modifications in existing moulds / dies of the existing machinery. For inclusion of new sizes of gloves, CSoL guidelines is to be followed.
7.2 Watertightness	Watertightness New test requirement has been introduced in the revised standard and the test method has also been defined in **Annex - B**		Existing licensees need to add the test facilities for testing the gloves as per the specified requirement and should submit the report of conformity for the same. Firm to also submit the conformity of the test parameter either through In-house test report or test report issued from BIS Approved lab
7.3 Tensile Properties	Tensile Properties Requirement of tensile properties (both pre and post ageing) has been revised		Firm to submit the conformity of the gloves as per the revised requirement (for which the firm is having licence) either through In-house test report or test report issued from BIS Approved lab
7.4 Sterility	Sterility Requirement of Sterility is incorporated		Firm has to declare the process of sterility that they intend to do and the equipment required for sterilization is to be declared.
9	Marking		Firm to submit the declaration for

Marking	Marking clause has been made modified with clearly specifying the requirements that are to be marked on inner package, unit package and multi packaging.	same and revised marking details to the Bureau.

3. Consequent upon the Revision of Indian Standard, the Product Manual has been revised as Product Manual Doc: PM/ IS 13422/ 2 Mar 2025 and is being circulated separately through BIS website.

4. The guidelines for implementation of the Revised Indian Standard is given below:

A) LICENSEES

i. All Licensee shall implement the requirements of the Revised Standards by 29 Jul 2025. Any difficulty in implementation shall be brought to the notice of CMD III within one month of issuance of these guidelines. BO shall ensure that no Licences are under operation as per old standard after 29 Jul 2025. The status of implementation of the revised Indian Standard shall be confirmed by Head (BO) to CMD-III within one month of the last date of concurrent running.

ii. In order to implement the revised standard, the firm shall submit the following:

- Licensee shall declare the revised scope based on the classifications made in the revised standard. Scope of the licence is to be restricted based on the declaration made and only such varieties are to be covered that are already covered under the scope of licence.

- Licensee shall also submit in-house test report / test report from BIS approved labs in order to establish conformity to the modified requirements i.e. Dimension, Tensile Strength, Watertightness and Sterility (if applicable) as specified in the table above.

- Licensee shall also submit the compliance of raw material requirement either through in-house test report or Test certificates from BIS approved 3rd party Lab.

- The manufacturers are required to submit their acceptance to revised scheme of inspection and testing; or their own quality assurance plan as per the revised product manual.

iii. Verification of implementation of the Revised Standard shall be done during the next 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 29 Jul 2025, 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 revision. 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 with or without Revision. Processing of Applications without Revision shall be permitted only upto 29 Jul 2025 and for such cases Applicant shall give a declaration that they will implement the Revised Indian Standard by 29 Jul 2025.

iii. After 29 Jul 2025, no Licence shall be granted without consideration of the Revision.

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 old Standard shall be permitted only upto the date of implementation of the revised Standard by the licensee or up to 29 Jul 2025 whichever is earlier.

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

Rahul Vishwakarma
Scientist D

Head (CMD III)
DDG (Certification)