<u>केन्द्रीय मुहर विभाग–2</u>

संदर्भ -: केमूवी-2/16: 863 14 01 2025

विषय: IS 863: 2023 के amendment no. 1 के अनुपालन के दिशानिर्देश।

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्न है ।

सभी क्षेत्रीय/शाखा कार्यालयों से अनोरोध है की दिशानिर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

हरीश मीना
वैज्ञानिक-सी

<u>प्रमुख (केमूवी 2)</u>
सभी क्षेत्रीय/शाखाकार्यालय/प्रयोगशालाएँ/TXD/LRMD

<u>CENTRAL MARKS DEPARTMENT-2</u>

Our Ref: CMD-2/16: 863 14 01 2025

Subject: Guidelines for implementation of amendment no. 1 to IS 863: 2023.

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.

Harish Meena
Scientist-C

<u>Head (CMD-2)</u>
All ROs/BOs/Labs/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 863 14 01 2025

Subject: Guidelines for implementation of amendment no. 1 to IS 863:2023 (MEDICAL TEXTILES — COTTON BANDAGE CLOTH — SPECIFICATION).

1. Amendment no. 1 to IS 863: 2023 has been published. The last date of implementation of the amendment is **22nd February 2025**.

2. The significant changes in the standard through this amendment as listed in the Table are given for the purpose of general guidance.

Clause No.	Change
4.2	Below mentioned new clause has been incorporated after clause 4.2 of IS 758: 2023: '**4.3 Cleanliness–Microbial/Bioburden Test** The bandage cloth shall confirm the requirement of cleanliness–microbial/bioburden for sterile and non-sterile product. For sterile product, 'no viable microorganism shall be present' and for non-sterile product, it shall be ≤ 300 (CFU/100 cm2) when tested in accordance with IS/ISO 11737 (Part 2) and IS/ISO 11737 (Part 1) respectively.'
4.2	'Viewing under ultraviolet light' has been substituted by 'Viewing under ultraviolet light at 365 nm' at Table 1, Sl No. (viii), col (4).
4.2	Requirement of 'Sterility' specified at Table 1, Sl No. (x) has been deleted.
Annex-A	Following changes have been done in the list of referred Standards: i. 'IS 10150 : 1981 Guide for sterilization of medical products' has been substituted by 'IS/ISO 11737-1 : 2018 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products'. ii. 'IS/ISO 11737-2 : 2019 (TXD 36) Sterilization of health care products — Microbiological methods: Part 2 Tests of sterility performed in the definition, validation and maintenance of a sterilization process' has been inserted before IS 14944 : 2020.

3. Consequent upon the issuance of the amendment, the existing product manual has been revised which is being circulated separately.

4. The guidelines for implementation of the amendment are given below:

A. LICENSEES:

i) All Licensees shall implement the amendment by **22nd February 2025**. Any difficulty in implementation shall be brought to the notice of CMD 2 at the earliest but in any case at least 30 days before the last date of implementation. BOs shall ensure that no Licences are under operation as per IS 863: 2023 without the amendment after **22nd February 2025**. The status of implementation of the amendment shall be confirmed by Head (BO) to CMD-2 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 as well as revised declaration of test equipment as per Form 2. Verification of implementation of the amendment, wherever required, shall be verified through a surveillance visit within 30 days of confirmation of implementation of the amendment to standard by licensee.

iii) Scope of licenses shall be aligned in accordance with the revised product manual, on the basis of available test reports.

iv) If the Licensee fails to complete all actions by **22nd February 2025** it shall be dealt with as per the prevailing guidelines.

B. <u>APPLICATIONS FOR GRANT OF LICENCE</u>:

i. Existing Applications where Sample has been submitted in the Laboratory/Test Report has been issued by the Laboratory may be processed without considering amendment no. 1. However, if the Applicant is desirous of considering the Application as per the amended Standard, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking from such Applicants shall also be obtained that if the sample fails while considering the provisions of the amended Standard, Licence will not be granted by BIS without considering the amendment.

ii. Applications which are recorded henceforth may be processed with or without considering the amendment no. 1. Processing of Applications without considering the amendment no. 1 shall be permitted only up to **21st February 2025** and for such cases Applicant shall give a declaration that they will implement the amended Standard by **22nd February 2025**.

iii. Beyond **22nd February 2025** no Licence shall be granted without considering the amendment no. 1 to IS 863: 2023.

C. <u>CHANGE IN SCOPE OF LICENCE</u>:

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 without considering amendment no. 1 shall be permitted only up to the date of implementation of the amendment by the licensee or up to **22nd February 2025,** whichever is earlier.

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

Harish Meena
Scientist-C

<u>Head (CMD-2)</u>
<u>DDG (Certification)</u>