

केन्द्रीय मुहर विभाग-2

संदर्भ -: केमूवी-2/16:863

21 12 2023

विषय: संशोधित IS 863:2023 के अनुपालन के दिशा निर्देश

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्न है।

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

**आदित्य दास
वैज्ञानिक D**

प्रमुख (केमूवी 2)

सभी क्षेत्रीय/शाखाकार्यालय/प्रयोगशालाएँ/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:863

21 12 2023

Subject: Guidelines for implementation of Revised 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.

**(Aditya Das)
Scientist D**

Head (CMD-2)

All ROs/BOs/Labs/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 863

21 12 2023

Subject: Guidelines for implementation of Revised IS 863:2023 (Medical Textiles — Cotton Bandage Cloth— Specification)

1. IS 863:1988 has been revised as IS 863:2023 and has been published. The last date for implementation of the revised Standard is **21 May 2024** after which the old Standard shall stand withdrawn.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.
3. The significant changes in the revised Standard as listed in the Table are 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.

Clause No.	Change
1	Title and scope of the standard has been updated - non-sterilized cotton bandage cloth, bleached or dyed changed to cotton bandage cloth, bleached or dyed.
3.2	The requirement of cloth (fabric) defects has been modified
4.1	Fibre identification test has been specified
Table 1, Sl No. (iv) and (v),	Requirement of length and width has been changed from Not less than 99 percent of agreed or declared value to Not less than 98 percent of agreed or declared value
Table 1 S No (x)	Sterility test (optional) has been specified
2, Annex A	References to Indian Standards have been updated;
6	Marking and packing clauses and BIS certification marking clause has been updated
7	Sampling and criteria of conformity has been modified.

4. Consequent upon the issuance of the revised Standard, the existing product manual has been revised which is being circulated separately through BIS website.
5. The guidelines for implementation of the revised Standard is given below:

A. LICENSEES:

- i. The licensee shall implement the revised Standard by **21 May 2024**. Any difficulty in implementation shall be brought to the notice of CMD 2 at the earliest. BOs shall ensure that no Licences are under operation as per the old Standard after **21 May 2024**. **The status of implementation of the revised Standard shall be confirmed by Head (BO) to CMD-2 within two weeks of the last date of concurrent running.**
- ii. The licensee shall submit evidence of conformity to the additional/modified requirements through In-house/Independent Test Reports or test certificate of supplier (for raw material/material identification) as well as revised list of test equipment (as per Form 2), if applicable. Verification of implementation of the revised Standard, wherever

required, **shall be verified through a surveillance visit within 30 days of confirmation of implementation of the revised standard by licensee.**

- iii. If the Licensee fails to complete all actions by **21 May 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 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 from such Applicants also be obtained that if the sample fails while considering the provisions of the revised Standard, 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 up to **20 May 2024** and for such cases Applicant shall give a declaration that they will implement the revised Standard by **21 May 2024**.
- iii. Beyond **21 May 2024** 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 up to **21 May 2024** whichever is earlier.

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

Aditya Das
Sc. D

Head (CMD-2)
DDG (Certification)