

केंद्रीय मुहर विभाग-2

हमारा संदर्भ: CMD 2/16: 16111

12-12-2019

विषय: IS 16111:2013 (Elastic Bandage) की अनुज्ञप्ति संख्या 3 के अनुपालन के दिशा निर्देश

उपरोक्त विषय के संदर्भ में सक्षम अधिकारी द्वारा अनुमोदित दिशा निर्देश अनुपालन हेतु संलग्न हैं।

**आदित्य दास
वैज्ञानिक सी**

प्रमुख (CMD 2)

सभी क्षेत्रीय/शाखा कार्यालय/प्रयोगशालाएँ/LPPD/TXD

प्रतिलिपि

ITSD – इंटरनेट पर अपलोड करने के लिए

CENTRAL MARKS DEPARTMENT 2

Our Ref: CMD 2/16: 16111

12-12-2019

Subject: Guidelines for implementation of Amendment No. 3 to IS 16111:2013 (Elastic Bandage)

Please find enclosed circular with guidelines regarding the subject matter, duly approved by Competent Authority, for implementation.

**Aditya Das
Sc. C**

Head (CMD 2)

ROs/BOs/Labs/LPPD/TXD

Copy to:

ITSD – With a request to upload the circular on intranet

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 16111

12 12 2019

Subject: Guidelines for implementation of Amendment No. 3 to IS 16111:2013 - Elastic Bandage

1. Amendment No. 3 to IS 16111:2013 has been published. The last date for implementation of the amendment is **29 Jan 2020**.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above amendment **within a week of issuance of these guidelines**.
3. The significant changes in the amendment 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 amendment.

Clause	Requirement
5	Requirements for dimensions and tolerances have been modified

4. There are no changes in the existing STI.
5. The guidelines for implementation of the amendment is given below:

A. LICENSEES:

- (i) All Licensees shall implement the amendment by **29 Jan 2020**. BOs shall ensure that no Licences are under operation as per IS 16111:2013 without the amendment after **29 Jan 2020**.
- (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 amendment, wherever required, may be done during the next visit **which may normally be completed within six months of the last date of concurrent running**.
- (iii) If the Licensee fails to complete all actions by **29 Jan 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 without consideration of the amendment. However, if the Applicant is desirous of considering the amendment, 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 amendment, Licence will not be granted as per the old version.
- (ii) Applications which are recorded henceforth may be processed with or without consideration of the amendment. Processing of Applications without consideration of the amendment shall be permitted only upto **29 Jan 2020** and for such cases Applicant shall give a declaration that they will implement the amendment by **29 Jan 2020**.

(iii) Beyond **29 Jan 2020** no Licence shall be granted without consideration of the amendment.

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 without consideration of the amendment shall be permitted only upto the date of implementation of the amendment by the licensee or upto **29 Jan 2020** whichever is earlier.

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

Aditya Das
Sc. C

Head (CMD-2)
DDG (Certification)

AMENDMENT NO. 3 JULY 2019
TO
IS 16111 : 2013 ELASTIC BANDAGE

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[Page 1, clause 5 (see also Amendment No. 1)] --- Substitute the following the existing:

DIMENSIONS AND TOLERANCES

Description	Width cm	Tolerance for Width cm	Stretched Length m	Tolerance for Stretched Length cm
Elastic Bandages	2-4	± 0.2	2.0 - 4.0	± 20
			Above 4.0 - 10.0	± 40
			Above 10.0 - 20.0	± 60
	Above 4 - 12	± 0.5	2.0 - 4.0	± 20
			Above 4.0 - 10.0	± 40
			Above 10.0 - 20.0	± 60
	Above 12 - 20	± 0.7	2.0 - 4.0	± 20
			Above 4.0 - 10.0	± 40
			Above 10.0 - 20.0	± 60

18/7/2013

(TXD 36)

Publication Unit, BIS, New Delhi, India