

**केन्द्रीय मुहर विभाग -2**

संदर्भ -: के मू वी-2/16:17630

19.08.2024

**विषय: IS 17630 : 2021 के amendment no. 2 के अनुपालन के दिशानिर्देश ।**

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्न है ।

अनुरोध है की दिशानिर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

**हरीश मीना  
वैज्ञानिक-बी**

**प्रमुख (के मू वी 2)**

**सभी क्षेत्रीय/शाखा कार्यालयों/ प्रयोगशालाएँ/TXD/LRMD**

**CENTRAL MARKS DEPARTMENT-2**

Our Ref: CMD-2/16:17630

19.08.2024

**Subject: Guidelines for implementation of amendment no. 2 to IS 17630 : 2021.**

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

It is requested to ensure the implementation of the above Guidelines with immediate effect.

**(Harish Meena)  
Scientist-B**

**Head (CMD-2)**

**All ROs/BOs/Labs/TXD/LRMD**

## CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:17630

Date: 19 .08.2024

**Subject: Guidelines for implementation of Amendment no. 2 to IS 17630 : 2021(Medical Textiles — Bedsheet and Pillow Cover — Specification).**

1. Amendment no. 2 to **IS 17630 : 2021(Medical Textiles — Bedsheet and Pillow Cover — Specification)** has been published. The last date of implementation of the amendment is **19<sup>th</sup> September, 2024**.
2. The significant changes in the standard through this amendment as listed in the Table are given for the purpose of general guidance.

<b>Clause No.</b>	<b>Change</b>
Table 2	<ol style="list-style-type: none"><li>i. The requirement of “Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization” has been made Optional at Sl. No. (viii), col (2)</li><li>ii. The word “non-cytotoxic” has been substituted in place of “None” at Sl No. (viii) (a), col (3)</li></ol>
9.1	<ol style="list-style-type: none"><li>i. Based on the applicability, below mentioned new marking requirement has been introduced: The information whether the material of the product is biocompatible that is, meets the requirement of the standard for biocompatibility evaluation – cytotoxicity, irritation and skin sensitization</li><li>ii. The word “MEDICAL USE” has been added in the marking clause.</li></ol>

3. Most of the changes to the standard through this amendment are relaxations, editorial and in marking only, none of which require any evidence of conformity to the amended standard to be established.
4. In view of the above, BOs are requested to circulate this amendment to all applicants immediately within 7 days of issue of this circular.
5. 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 amended Standard, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly.
6. Beyond **19<sup>th</sup> September 2024** no Licence shall be granted as per the old Standard.
7. The above guidelines come into force with immediate effect.

**Harish Meena**  
**Scientist-B**

**Head (CMD-2)**

**DDG (Certification)**