केन्द्रीय मुहर विभाग–2

संदर्भ -: केमूवी-2/16:17508 06 06 2024

विषय: IS 17508: 2020 के amendment no. 1 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।

हरीश मीना
वैज्ञानिक- बी

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

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:17508 06 06 2024

Subject: Guidelines for implementation of amendment no. 1 to IS 17508: 2020.

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-B

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

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:17508 06 06 2024

Subject: Guidelines for implementation of amendment no. 1 to IS 17508: 2020 (DISPOSABLE ADULT INCONTINENCE DIAPER — Specification)

1. Amendment no. 1 to IS 17508: 2020 has been published. The last date of implementation of the amendment is **9 August 2024**.

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
7.4	i. The requirement of "Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization" has been made Optional. ii. The first sentence of the clause has been changed to "If required by the buyer, the manufacturer shall ensure that raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use." iii. In the second paragraph "non-cytotoxic" has been substituted in place of "None"
7.7	New requirement of Phthalate test has been introduced in the ISS.
9.1	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

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 **9 August 2024**. 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 17508: 2020 without the amendment after **9 August 2024**. 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(if applicable). 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 as per amended standard shall be modified to align with the scope in revised product manual.

iv) If the Licensee fails to complete all actions by **9 August 2024** 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 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. An undertaking shall from such Applicants also be obtained that if the sample fails while considering the provisions of the amended 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 amended Standard. Processing of Applications as per the old Standard shall be permitted only up to **8 August 2024** and for such cases Applicant shall give a declaration that they will implement the amended Standard by **9 August 2024**.

iii. Beyond **9 August 2024** no Licence shall be granted as per the old Standard.

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 as per the old Standard shall be permitted only up to the date of implementation of the amendment or up to **9 August 2024** whichever is earlier.

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

Harish Meena
Scientist- B

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