

केन्द्रीय मुहर विभाग -2

संदर्भ -: के मू वी-2/16:17509

12.04.2024

विषय: IS 17509: 2021 के amendment no. 1 के अनुपालन के दिशा निर्देश ।

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशा निर्देश अनुपालन हेतु संलग्न है ।

अनुरोध है की दिशा निर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

**हरीश मीना
वैज्ञानिक बी**

प्रमुख (के मू वी 2)

सभी क्षेत्रीय/शाखा कार्यालय/प्रयोगशालाएँ/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:17509

12.04.2024

Subject: Guidelines for implementation of amendment no. 1 to IS 17509: 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-2/16:17509

Date: 12.04.2024

Subject: Guidelines for implementation of Amendment no. 1 to IS 17509: 2021 (DISPOSABLE BABY DIAPER — SPECIFICATION)

1. Amendment no. 1 to IS 17509: 2021 has been published. The last date of implementation of the amendment is **09.05.2024**.
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	<ol style="list-style-type: none">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”
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
B-2.2	A tolerance of 0.1 percent on the total weight of rigid cover has been permitted if agreed between the buyer and seller.

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 licensees and applicants immediately within 7 days of issue of this circular.
5. No application for grant of licence and/or change in scope of licence shall be accepted or grant of licence/change in scope permitted without consideration of the amendment after **09 May, 2024**.
6. The above guidelines come into force with immediate effect.

Harish Meena
Scientist-B

Head (CMD-2)
DDG (Certification)