

**केन्द्रीय मुहर विभाग –2**

संदर्भ -: के.वि.मु.-2/16: 5405

13 12 2019

**विषय: संशोधित IS 5405:2019 के अनुपालन के दिशा निर्देश**

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशा निर्देश अनुपालन हेतु संलग्न है।

सभी क्षेत्रीयशाखा कार्यालयों से अनुरोध है की उपरोक्त दिशानिर्देशों का अनुपालन तत्काल प्रभाव से सुनिश्चित/ करें।

(आदित्य दास)  
वैज्ञानिक सी

**प्रमुख (CMD 2)**

**सभी क्षेत्रीय/शाखा कार्यालय/प्रयोगशालाएँ/LPPD/TXD**

प्रतिलिपि :

**आई टी एस विभाग – बी आई एस इंटरनेट पर डालने हेतु**

**CENTRAL MARKS DEPARTMENT-2**

Our Ref: CMD-2/16:5405

13 12 2019

**Subject: Guidelines for implementation of Revised IS 5405:2019**

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 C

**Head (CMD-2)**

**All ROs/BOs/Labs/TXD/LPPD**

Copy to:

**ITSD - for hosting on BIS Intranet.**

## CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 5405

13 12 2019

### **Subject: Guidelines for implementation of Revised IS 5405:2019 - Sanitary Napkins**

1. IS 5405:1980 has been revised as IS 5405:2019 and has been published. The last date for implementation of the revised Standard is **27 July 2020** after which the old Standard shall stand withdrawn.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	Changes
1	Scope has been restricted to cover only disposable (non-reusable) sanitary napkins for external use thus excluding reusable sanitary napkins (Separate standard is under development)
3	The materials for sanitary napkins have been classified into 3 components and their requirements prescribed
4	Sanitary napkins have been classified into two types: thick and thin based on the material of the core
5	Recommended sizes have been modified
6	Manufacture clause has been modified
7.1	pH value requirement has been modified
7.2	The procedure and requirement of ability to withstand pressure after absorption have been modified
7.3	Hygiene testing requirements have been added (Total viable count (total number of bacteria and fungi) and <i>Staphylococcus aureus</i> )
7.3.3	Good manufacturing practice guidelines for hygiene requirement has been specified
7.4	Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization requirements have been added
7.5	Optional requirement of biodegradability and compostability have been specified (in place of disposability)
8	Sampling and criteria for conformity has been specified
9	Marking and packing clause has been modified

4. Consequent upon the issuance of the revised Standard, existing STI has been revised as a Scheme of Inspection and Testing (SIT) Doc: SIT/5405/1 Dec 2019 which is being circulated separately.

5. The guidelines for implementation of the revised Standard are given below:

**A. LICENSEES:**

- (i) All Licensees shall implement the revised Standard by **27 July 2020**. BOs shall ensure that no Licences are under operation as per the old Standard after **27 July 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 revised Standard, 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 **27 July 2020** it shall be dealt with as per the prevailing guidelines.
- (iv) *As mentioned above, the revised standard has excluded reusable sanitary napkins from its scope. TXD has informed that reusable napkins were excluded since this standard does not adequately capture the requirements for disposable napkins and therefore the technical committee has decided to formulate a separate standard for disposable napkins. Accordingly, reusable napkins shall be deleted from the scope of existing licenses by **27 July 2020** and such manufacturers of reusable napkins will need to obtain a separate licence as per the new standard being formulated.*

**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 in new test requirements, 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 upto **26 July 2020** and for such cases Applicant shall give a declaration that they will implement the revised Standard by **27 July 2020**.
- (iii) Beyond **27 July 2020** 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 upto **27 July 2020** whichever is earlier.

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

**Aditya Das**  
**Sc. C**

**Head (CMD-2)**  
**DDG (Certification)**