

केन्द्रीय मुहर विभाग -2

संदर्भ -: के मू वी-2/16:5405

20 02 2023

विषय: IS 5405:2019 के amendment no. 2 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।

**आदित्य दास
वैज्ञानिक D**

प्रमुख (के मू वी 2)

सभी क्षेत्रीय/शाखा कार्यालय/प्रयोगशालाएँ/ TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:5405

20 02 2023

Subject: Guidelines for implementation of amendment no. 2 to IS 5405:2019

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.

(Aditya Das)
Scientist D

Head (CMD-2)

DDG (Certification)

All ROs/BOs/Labs/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref:CMD-2/16:5405

Date: 20 02 2023

Subject: Guidelines for implementation of Amendment no. 2 to IS 5405:2019 (Sanitary napkins – Specification)

1. Amendment no. 2 to IS 5405:2019 has been published.
2. Through the amendment, the following has been added to the marking clause:

f) 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 (if applicable).'

3. Revised product manual incorporating the amendment is being circulated separately.
4. No evidence of conformity of the amended standard is required to be collected from licensees and applicants. However, BOs are requested to circulate this amendment to licensees and applicants immediately within 7 days of issue of this circular.
5. In cases where the biocompatibility requirement (optional requirement) is covered in the scope of licence, implementation of the above change to marking requirements shall be verified during the next factory visit.
6. The above guidelines come into force with immediate effect.

**Aditya Das
Sc. D**

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

AMENDMENT NO. 2 OCTOBER 2022

TO

IS 5405 : 2019 SANITARY NAPKINS — SPECIFICATION
(*Second Revision*)

(Page 4, *clause 9.1*) — Insert the following at the end:

‘f) 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 (if applicable).’

(TXD 36)

Publication Unit, BIS, New Delhi, India