केन्द्रीय मुहर विभाग–2

संदर्भ -: केमूवी-2/16:17423 17 11 2021

विषय: संशोधित IS 17423:2021 (Medical Textiles – Bio-Protective Coveralls – Specification) के अनुपालन के दिशानिर्देश

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्नहै।

सभी क्षेत्रीय/शाखा कार्यालयों से अनोरोध है की दिशानिर्देशों 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-2/16:17423 17 11 2021

Subject: Guidelines for implementation of Revised IS 17423:2021 (Medical Textiles – Bio-Protective Coveralls – Specification)

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 D

Head (CMD-2)

All ROs/BOs/Labs/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 17423 05 11 2021

Subject: Guidelines for implementation of Revised IS 17423:2021 (Medical Textiles ─ Bio-Protective Coveralls ─ Specification)

1. IS 17423:2020 (Medical Textiles - Coveralls for COVID-19) has been revised as IS 17423:2021 (Medical Textiles ─ Bio-Protective Coveralls ─ Specification and has been published. The last date for implementation of the revised Standard is **12 July 2022** after which the old Standard shall stand withdrawn.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	Change
Cl. 1	Title of the standard has been modified from "Coveralls for COVID-19" to "Bio Protective Coveralls". The scope has been modified to cover the requirement of multiple/reusable bio-protective coverall.
Cl 3 and 4	Terms and definitions, and manufacture clause have been modified.
Cl 5.2, 5.3, Table 1	Requirement of resistance to penetration by blood borne pathogens (resistance to viral penetration), breathability (water vapour transmission rate), tensile strength (dry and wet), seam strength (dry and wet), cleanliness – microbial, resistance to dry microbial penetration and biocompatibility evaluation (for raw material) have been specified.
5.4, Table 2	Four level of performances of coveralls have been specified (The regulators/user should decide the levels as given in Table 2 to be selected based on anticipated risk from infectious agents, pathogens, microorganism, distance and duration of contact with infectious agents/pathogens/microorganism, barrier protection and performance requirement as given in Table 1.)
5.5, Annex B	Guidelines for reprocessing, storage, handing, transportation, washing, disinfection of multiple use/reusable coveralls have been specified.
Cl. 6,7	Packaging and marking clause have been modified. (Sterilization requirement has also been added)
Cl. 2	References to Indian Standards have been updated

4. Consequent upon the issuance of the revised Standard, the existing product manual has been revised which is being circulated separately.

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

A. LICENSEES:

i) All Licensees shall implement the revised Standard by **12 July 2022**. 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 the old Standard after **12 July 2022.**

ii) **The status of implementation of the revised Standard shall be confirmed by Head (BO) to CMD-2 within two weeks of the last date of concurrent running.**

iii) Licensees shall submit evidence of conformity to the additional/modified requirements through In-house/Independent Test Reports (and supplier's test certificates or test reports of NABL Accredited Labs for establishing conformity of raw material to additional/modified requirements). Verification of implementation of the revised Standard, wherever required, may be done during the next visit.

iv) If the Licensee fails to complete all actions by **12 July 2022** it shall be dealt with as per the prevailing guidelines.

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 **11 July 2022** and for such cases Applicant shall give a declaration that they will implement the revised Standard by **12 July 2022**.

iii) Beyond **12 July 2022** 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 **12 July 2022** whichever is earlier.

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

Aditya Das
Sc. D

Head (CMD-2)
DDG (Certification)