

केन्द्रीय मुहर विभाग - III

हमारा संदर्भ- केन्द्रीय मुहर विभाग-3/16: IS 9471 (Part 4)

10 December 2020

विषय: अनुपालन हेतु गाइडलाइन

सभी शाखा कार्यालय से आग्रह है कि गाइडलाइन का अनुपालन तत्काल प्रभाव से सुनिश्चित करें।

जे एस कविन कीर्ति विनायगम
वैज्ञानिक 'सी' (सी एम डी-III)

प्रमुख (सी एम डी-III)

सभी क्षेत्रीय/शाखा कार्यालय

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-3/16: IS 9471 (Part 4)

10 December 2020

**Subject: Guidelines for implementation of Amendment No. 3 to IS 9471 (Part 4): 1980
- Modular Lower Limb Orthotic Components - Joint Unit, Ankle**

This has reference to the subject mentioned above.

BOs may kindly ensure implementation of the guidelines with immediate effect.

JS Kavin Keerthy Vinayagam
Scientist-C (CMD III)

Head (CMD - III)

Circulated to: All ROs/BOs

CENTRAL MARKS DEPARTMENT III

Our Ref: CMD III/16: IS 9471 (Part 4)

09 December 2020

Subject: Guidelines for implementation of Amendment No. 3 to IS 9471 (Part 4): 1980 - Modular Lower Limb Orthotic Components - Joint Unit, Ankle

1. Amendment No. 3 to IS 9471 (Part 4): 1980 has been published. The last date for implementation of the amendment is 10 March 2021.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above amendment **within a week of issuance of these guidelines**.
3. The significant changes in the amendment as listed in the Table is given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the amendment.

Clause	Requirement
Cl. 4.1	Material requirement of the male and female joint unit have been modified.

4. Consequent upon issuance of the amendment, existing Product manual has been revised as Doc: PM/ IS 9471 (Pt 4)/ 2/ December 2020.
5. The guidelines for implementation of the amendment is given below:

A. LICENSEES:

- (i) All Licensees shall implement the amendment by 10 March 2021. BOs shall ensure that no Licences are under operation as per IS 9471 (Part 4): 1980 without the amendment after 10 March 2021. **The status of implementation of the amendment shall be confirmed by Head (BO) to CMD-III 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 or Test Certificates, as applicable. Verification of implementation of the amendment, 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 10 March 2021 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 without consideration of the amendment. However, if the Applicant is desirous of considering the amendment, a declaration may be obtained from the Applicant to that effect and the Application may be processed

accordingly. An undertaking shall also be obtained from such Applicants that if the sample fails while considering the provisions of the amendment, Licence will not be granted as per the old version.

- (ii) Applications which are recorded henceforth may be processed with or without consideration of the amendment. Processing of Applications without consideration of the amendment shall be permitted only upto 10 March 2021 and for such cases Applicant shall give a declaration that they will implement the amendment by 10 March 2021.
- (iii) Beyond 10 March 2021 no Licence shall be granted without consideration of the amendment.

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 without consideration of the amendment shall be permitted only upto the date of implementation of the amendment by the licensee or upto 10 March 2021 whichever is earlier.

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

(JS Kavin Keerthy Vinayagam)
Scientist C

Head (CMD III)
DDG (Certification)