भारतीय मानक ब्यूरो (केंद्रीय मुहर विभाग III)

हमारा संदर्भ : सी एम डी - 111/16 : आई एस 9471 (भाग 6)

27 नवंबर 2024

विषय : संशोधित आई एस 9471 (भाग 6) के अनुपालन हेतु गाइडलाइन

इसमें ऊपर उल्लिखित विषय का संदर्भ है।

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

(ऐ के कअंर) वैज्ञानिक-डी (सी एम् डी-॥।)

प्रमुख (सी एम डी- ॥।)

सभी क्षेत्रीय /शाखा कार्यालय

BUREAU OF INDIAN STANDARDS (Central Marks Department-III)

Our Ref: CMD-III/16 : IS 9471 (Part 6)

27 Nov 2024

Subject: Guidelines for implementation of Revised IS 9471 (Part 6): 2024 - 'Modular Lower Limb Orthotic Components: Part 6 – Orthotic Hip Joint (Joint Unit, Hip Drop Lock)'

This has reference to the subject mentioned above.

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

(A K Kanar) Sc-C (CMD-III)

Head (CMD-III)

Circulated to: All ROs/BOs

CENTRAL MARKS DEPARTMENT III

Our Ref: CMD-III/16 : IS 9471 (Part 6) 27 Nov 2024

Subject: Guidelines for implementation of Revised IS 9471 (Part 6): 2024 - 'Modular Lower Limb Orthotic Components: Part 6 – Orthotic Hip Joint (Joint Unit, Hip Drop Lock)'

- 1. IS 9471 (Part 6): 2000 has been revised as IS 9471 (Part 6): 2024 and has been published. The last date for implementation of the revised Standard is **04 Mar 2025** after which the old Standard shall stand withdrawn.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 is 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.

Sr No	Major changes in revised Indian Standard	Action required from existing licensee for implementation
1.	Corrosion resistant high alloy steel and nickel base investment castings as per IS 10774:1993 are also permitted as raw material for manufacturing joint body upper. (Cl 4.1)	No action is reqd if already existing raw material as per IS 6911 is being used. If manufacturer opts to use the new material as per IS 10774:1993, then they are required to provide the conformity of the material through test certificate of supplier/ test reports of independent lab.
2.	Material requirement for joint hip lower as per IS 1079 has been specified (Cl 4.2)	Firm is required to ensure conformity to this requirement through outside TR/ test certificate of supplier.
3.	Corrosion resistant high alloy steel and nickel base investment castings as per IS 10774:1993 are also permitted as raw material for manufacturing lock drop ring. (Cl 4.3)	No action is reqd if already existing raw material as per IS 6911 is being used. If manufacturer opts to use the new material as per IS 10774:1993, then they are required to provide the conformity of the material through test certificate of supplier/ test reports of independent lab.
4.	Material requirement for Nuts as per IS 9550/ IS 10774 has been specified (Cl 4.5)	Firm is required to ensure conformity to this requirement through outside TR/ test certificate of supplier.

- 4. Consequent upon the issuance of the revised Standard, existing Product Manual has been revised as Doc: PM/IS 9471 (Pt 6)/2/Oct 2024.
- 5. The guidelines for implementation of the revised Standard is given below:

A. <u>LICENSEES</u>:

- (i) All Licensees shall implement the revised Standard by **04 Mar 2025**. Any difficulty in the implementation shall be brought to the notice of CMD III within 30 days of issuance of these guidelines. BOs shall ensure that no licences are in operation as per the old Standard after **04 Mar 2025**. The status of implementation of the revised Standard shall be confirmed by Head (BO) to CMD-III within two weeks of the last date of concurrent running.
- (ii) Licensees shall submit the declarations for the type of raw materials being used for joint body upper (Cl 4.1) & lock drop ring (Cl 4.3). Licensees shall also provide the evidence of conformity of raw materials, i.e. joint body upper (if IS 10774 is used) (Cl 4.1), joint hip lower (Cl 4.2), lock drop ring (if IS 10774 is used) (Cl 4.3) & Nuts (Cl 4.5) through independent test report/ test certificate of supplier. Verification of implementation of the revised Standard shall be done through a surveillance visit, which shall be completed within six months from the date of implementation.
- (iii) The manufacturers are required to submit their acceptance to revised scheme of inspection and testing; or their own quality assurance plan as per the revised product manual.
- (iv) If the Licensee fails to complete all actions by **04 Mar 2025**, 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 also be obtained from such Applicants that if the sample fails 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 **04 Mar 2025** and for such cases, Applicant shall give a declaration that they will implement the revised Standard by **04 Mar 2025**.
- (iii) Beyond **04 Mar 2025** no Licence shall be granted as per the old Standard.
- 6. The above guidelines come into force with immediate effect.

Ashish K Kanar Sc-D/Jt Dir, CMD-III

Head (CMD III) **DDG** (Certification)