



केन्द्रीय मुहर विभाग - III

हमारा संदर्भ- केन्द्रीय मुहर विभाग-३/१६: भा.मा. 19814 & 19815

०७ सितम्बर २०२६

विषय: अनुपालन हेतु गाइडलाइन

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

(गोथम बी जे)
वैज्ञानिक-डी/संयुक्त निदेशक

प्रमुख (के मु वि III)

सभी क्षेत्रीय/शाखा कार्यालय

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-3/16: IS 19814 & 19815

07 September 2026

Subject: Guidelines for switch over of IS 3319:1995 – Blades, Surgical, Detachable (Bard Parker Type) and Handles to IS 19814:2026 – Scalpel Handle/ IS 19815:2026 – Scalpel Blade

This has reference to the subject mentioned above.

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

(Gowththam B J)
Scientist-D/Joint Director

Head (CMD - III)

Circulated to: All ROs/BOs

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-3/16: IS 19814 & 19815

07 September 2026

Subject: Guidelines for switch over of IS 3319:1995 – Blades, Surgical, Detachable (Bard Parker Type) and Handles to IS 19814:2026 – Scalpel Handle/ IS 19815:2026 – Scalpel Blade

1. IS 3318: 1965 (General Requirements for Surgical Scalpels and Knives), IS 3319: 1995 (Blades, Surgical, Detachable (Bard Parker Type) and Handles) and IS 3320: 1973 (Surgical Scalpels) has been amalgamated and revised as IS 19814: 2026 (Scalpel Handle) and IS 19815:2026 (Scalpel Blade).
2. **The last date for implementation of the revised Standards IS 19814:2026 and IS 19815:2026 is 03 January 2027** after which the old Standards (IS 3318:1965, IS 3319:1995 & IS 3320:1973) shall stand withdrawn.
3. All BOs shall inform the Applicants and Licensees of IS 3319:1995 under their jurisdiction about the switch over to revised standards **within a week of issuance of these guidelines**.
4. The significant changes brought through this amalgamation as listed in the Table-1 for IS 19814:2026 and Table-2 for IS 19815:2026 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(s).

Table-1: Changes in IS 19814:2026 - Scalpel Handle

Sl. No.	Cl. Ref.	Changes in revised Standard (IS 19814:2026 - Scalpel Handle)	Actions required from existing licensees/BOs
1.	Title	Title of the standard has been modified as 'Scalpel Handle'.	Scope shall be revised by BOs.
2.	Cl.1, Scope	Scope of the standard has been modified.	
3.	Cl. 3, Terminology	Terminology has been modified	
4.	Cl. 5, Table 1 Dimensional Requirements	Value of α has been modified for Small handle. Commercial Designations for handles have been removed.	Conformity to new and modified requirements shall be established by licensee either through in-house or TPT lab test report, as applicable.
5.	Cl. 6, Mechanical Requirements	Requirement of Hardness has been modified. New requirements of Boiling water test for corrosion and Copper sulphate test (Cl. 4 & 5 of IS/ISO 13402) have been specified.	
6.	Cl.8, Performance Requirements	New requirement of Fitment Test for handles has been specified.	
7.	Cl. 9, Sterilization	IS 10150:1981 has been superseded by IS/ISO 11737-1: 2018 & IS/ISO 11737-2: 2019 which has been incorporated appropriately.	

Table-2: Changes in IS 19815:2026 - Scalpel Blade

Sl. No.	Cl. Ref.	Changes in revised Standard (IS 19815:2026 - Scalpel Blade)	Actions required from existing licensees/BOs
1.	Title	Title of the standard has been modified as 'Scalpel Blade'.	Scope shall be revised by BOs.
2.	Cl.1, Scope	Scope of the standard has been modified.	
3.	Cl. 3, Terminology	Terminology has been modified	No actions required.
4.	Cl. 4, Material Requirements	Additional grades permitted for Stainless Steel blades as per IS/ISO 7153-1.	Conformity to new and modified requirements shall be established by licensee either through in-house or TPT lab test report, as applicable.
5.	Cl. 5, Dimensional Requirements	New requirement of Fitment Test for handles has been specified.	
6.	Cl. 6, Mechanical Requirements	Requirement of Hardness has been modified for carbon steel.	
7.	Cl. 9, Sterilization	IS 10150:1981 has been superseded by IS/ISO 11737-1: 2018 & IS/ISO 11737-2: 2019 which has been incorporated appropriately.	

5. Consequent upon amalgamation of the above Standards, Product Manual for IS 3319 has been revised as **PM/IS 19814/1/Aug 2026** and **PM/IS 19815/1/Aug 2026**. In this PM revision, changes have been made in Scope of Licence, Grouping Guidelines, List of Test Equipments and Scheme of Inspection and Testing.

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

A. LICENSEES:

- (i) (a) **Scenario 1:** All Licensees of IS 3319:1995 having *existing licence scope covering Blades only* shall switch over to IS 19815: 2026 under the existing licence number.
- (b) **Scenario 2:** All Licensees of IS 3319:1995 having *existing licence scope covering Handles only* shall switch over to IS 19814: 2026 under the existing licence number.
- (c) **Scenario 3:** All Licensees of IS 3319:1995 having *existing licence scope covering both Handles and Blades* shall switch over to IS 19815: 2026 with revised scope covering Scalpel Blades only, under the existing licence number. Such licensees shall submit a separate application for grant of licence to cover Scalpel Handles as per IS 19814: 2026 which will be processed as All India First Application.
- (ii) All licensees shall switch over to new standards by **03 January 2027**, as applicable. Any difficulty in 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 under operation as per the old Standard after **03 January 2027**. 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.
- (iii) In order to establish conformity to the revised Standard(s), licensee shall submit in-house or independent test report as well as revised list of test equipment (as per Form 2) / testing arrangement, as applicable, of the product to **new and modified requirements** [*Dimensional Requirements (Cl. 5, Table 1), Mechanical Requirements (Cl. 6),*

Performance Requirements (Cl.8), Sterilization (Cl. 9) for IS 19814 & Dimensional Requirements (Cl. 5, Table 1), Material Requirements (Cl.4), Mechanical Requirements (Cl. 6), Sterilization (Cl. 9) for IS 19815], as applicable to the varieties covered, as evidence of conformity to the revised Standard. BOs shall align the scope of licence of the licensee in line with the scope defined in the latest Product Manual.

- (iv) Verification of implementation of the switch over to the applicable Standard(s), shall be done during the next surveillance visit.
- (v) If the Licensee fails to complete all actions by **03 January 2027**, 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(s), 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 revised Standard(s), Licence will not be granted as per the old version.
- (ii) Applications which are recorded henceforth may be processed as per old or revised Standard(s). Processing of Applications as per the old Standard shall be permitted only up to **03 January 2027** and for such cases Applicant shall give a declaration that they will implement the revised Standard(s) by **03 January 2027**.
- (iii) Beyond **03 January 2027**, no Licence shall be granted without consideration of the revised Standard(s).

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 old Standard shall be permitted only upto the date of implementation of the revision by the licensee or up to **03 January 2027**, whichever is earlier.
7. The above guidelines come into force with immediate effect.

(Gowtham B J)
Scientist-D/Joint Director

Head (CMD III)
DDG (Certification)