उत्पाद मैनुअल
सर्जिकल उपकरण — स्केलपेल ब्लेड
आईएस 19815: 2026 के अनुसर

PRODUCT MANUAL
Surgical Instruments — Scalpel Blade
According to IS 19815:2026

यह उत्पाद नियमावली सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसधारियों द्वारा विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना-I के अंतर्गत प्रमाणन के संचालन में एकरूपता और पारदर्शिता सुनिश्चित करने के लिए संदर्भ सामग्री के रूप में उपयोग की जाएगी। बीआईएस प्रमाणन प्राप्त करने के इच्छुक भावी आवेदक भी इस दस्तावेज़ का उपयोग कर सकते हैं।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations,2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या / IS No.**	:	IS 19815:2026
	शीर्षक / Title	:	Surgical Instruments — Scalpel Blade
	संशोधनों की संख्या **No. of amendments**	:	0
2.	**नमूनाकरण दिशानिर्देश / Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	• Mild Steel as per Cl. 4.2 of IS 19815 • Stainless Steel as per Cl. 4.3 of IS 19815
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	2 nos + One Packet for sterility test
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**		Same as the parameters given in scope of the licence under S. No. 6. *Note: Apart from the above, any other requirements/ parameters may also be declared as per the standard, as applicable.*
3.	**परीक्षण उपकरण की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण एवं परीक्षण योजना** **Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	• All tests *Note: This section is for the guidance of BIS Certification Officers/ Technical Auditors of BIS Authorized Outside Surveillance Agencies (OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by the officer/ auditor.*

6.	**लाइसेंस का दायरा / Scope of the Licence:**
"License is granted to use Standard Mark as per **IS 19815:2026** with the following scope:	
Name of the product	Surgical Instruments — Scalpel Blade
Size	Small / Large
Material	Mild Steel / Stainless Steel

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ANNEX -A
Grouping Guidelines

1. "Scalpel Blades" covered in IS 19815:2026 are categorized as given below:
    - Size: Small / Large
    - Material: Mild Steel / Stainless Steel

2. Considering the above, the guidelines given below shall be followed for GoL/CSoL:

    - Sample of Scalpel Blade of each Size (Small/Large) shall be tested for all requirements to cover the tested Size.

    - Sample of Scalpel Blade made from each material shall be tested for all requirements to cover the tested material.

3. The Firm shall declare the varieties of Scalpel Blades they intend to cover in the Licence.

4. The Scope of Licence may be restricted based on the manufacturing and testing capabilities of the manufacturer.

5. During the operation of the Licence, BO shall ensure that all the varieties covered in the Licence are tested in rotation, to the extent possible.

ANNEX- B

List of Test Equipments

(Indicative List, For Guidance Only)

Major test equipment required to test as per the Indian Standard

Sl. No.	Cl. Ref.	Tests used in with Clause Reference	Test Equipment
1.	4	Material Requirements	Spectrometer Certified Reference Material
2.	5	Dimensional Requirements	Micrometer Vernier Calliper (Digital) 10X Profile Projector Bevel Protractor Master Scalpel Handle as per IS 19814
3.	6	Mechanical Requirements	Vickers Hardness tester
4.	7	General Requirements	Profile Projector
5.	8	Performance Requirements	100 mm Piece of Chamois leather Steel Scale
6.	9	Sterilization	As per IS/ISO 11737-1 and IS/ISO 11737-2

The above list is indicative only and may not be treated as exhaustive.

ANNEX C
Scheme of Inspection and Testing

1. QUALITY ASSURANCE PLAN

1.1 It is expected that during operation of BIS licence manufacturers will implement a Quality Assurance Plan (QAP) i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan (QAP) defining the control unit (i.e. lot/batch etc.), the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or sub-contracting/ sharing for each applicable test and submit the same to BIS Branch Office for information. The manufacturer shall comply with the QAP and maintain test records in accordance with para 2.1.

1.3 Recommended Levels of Control/ Control Unit:

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: *entire quantity of Scalpel Blades of same size manufactured from same grade of raw material in a shift* constitute a control unit.

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1. Manufacturer has the discretion of declaring their own levels of control or accept the levels of control given in this document.

1.3.3 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING

The manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard for which they may have in-house test facilities. However, there is no obligation to maintain in-house laboratory. Licensee may use alternative arrangements for tests of the production as per the declared QAP. Various alternatives are available for operation of BIS certification as given below and the relevant guidelines for availing such relaxations by the manufacturers, as amended from time to time, are to be referred:

i) Shared testing resources like common facility,
ii) Cluster based testing facility,
iii) Sub-contracting to outside laboratories which may either be:
  a) BIS recognized/ empanelled laboratories, or
  b) Any accredited laboratory as per ISO/IEC 17025

2.1 Test Records- The manufacturers shall maintain test records for the tests carried out (either in-house or at a sub-contracted or at shared test facility) to establish conformity of the product to the Standard for operation of licence. For the tests being subcontracted or conducted at a shared test facility, test results issued by the laboratories or test facilities, shall be made available for inspection by BIS.

3. PACKING AND MARKING

The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on the packaging of the Scalpel Blades provided always that the Scalpel Blades so marked conforms to each requirement of the specification.

3.1 Marking and Labelling of Scalpel Blades shall be done as per Cl. 10 of IS 19815:2026.

3.2 Packaging of Scalpel Blades shall be done as per Cl. 12 of IS 19815:2026

3.3 **Additional Marking requirements**: The Scalpel Blades shall also be marked with the following additional requirement on its packaging:

a) "For BIS certification details please visit www.bis.gov.in"

4. REJECTION

The production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE-1

(Recommended Levels of Control by BIS- for Guidance Only)

(1)				(2)		
Test Details				**Levels of Control**		
Cl.	**Requirement**	**Test Methods**		**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**			
4.2	Material Requirements	4.2	IS 19815	Each Consignment		No further testing is required if accompanied with the Test Certificate or ISI marked.
4.3	Material Requirements		IS 6911 IS/ISO 7153-1			
5	Dimensional Requirements	5, Fig 1 Table 1	IS 19815	05	Each Control Unit	In case of failure, marking shall be stopped. The marking shall be resumed only after 10 samples produced consecutively have been found confirming.
7	General Requirements	7	IS 19815	Each blade		
6	Mechanical Requirements	6	IS 19815	05	Each Control Unit	If any sample fails, blades in that control unit shall not be marked
8	Performance Requirements	8	IS 19815	05	Each Control Unit	
9	Sterilization		IS/ISO 11737-1 IS/ISO 11737-2	20	Each Sterilization Batch	
10	Marking and Labelling	10	IS 19815	Each Blade & Each Package		
12	Packaging	12	IS 19815	Each Blade & Each Package		