



**PRODUCT MANUAL FOR  
BLADES, SURGICAL, DETACHABLE  
(BARDPARKER TYPE) AND HANDLES  
ACCORDING TO IS 3319:1995**

*This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence 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 licence.*

1.	<b>Product</b>	:	IS 3319:1995
	<b>Title</b>	:	Blades, Surgical, Detachable (Bard Parker type) and Handles
	<b>No. of Amendments</b>	:	1
2.	<b>Sampling Guidelines:</b>		
a)	<b>Raw material</b>	:	As per Cl 4 of IS 3319:1995
b)	<b>Grouping guidelines</b>	:	Please refer ANNEX –A
c)	<b>Sample Size</b>	:	2 nos + One Packet for sterility test
3.	<b>List of Test Equipment</b>	:	Please refer ANNEX –B
4.	<b>Scheme of Inspection and Testing</b>	:	Please refer ANNEX –C
5.	<b>Possible tests in a day:</b>		Shape and Dimension (Cl 5), Workmanship and Finish (Cl. 6), Hardness (Cl 7.1), Visual Examination (Cl. 9.1), Performance test (Cl. 9.2)
6.	<b>Scope of the Licence:</b>		
	“Licence is granted to use Standard Mark as per IS 3319:1995 with the following scope:		
	<b>Name of the product</b>		<ul style="list-style-type: none"> <li>• Detachable Surgical Blades (Bard Parker Type)</li> <li>• Handle</li> </ul>
	<b>Size</b>		<ul style="list-style-type: none"> <li>• Blade – Small/ Large</li> <li>• Handle - Small/ Large</li> </ul>
	<b>Type of blade</b>		<ul style="list-style-type: none"> <li>• Sterile/ Non-Sterile</li> </ul>

**ANNEX A**

**Grouping Guidelines**

1. The guidelines given below shall be followed for GoL/CSoL of Detachable Surgical Blades (Bard Parker Type) and their handles covered under IS 3319: 1995:

**(a) Blade**

Sample of Blade of each Size (Small/Large) from any Designation shall be tested for all requirements to cover each Size (Small/ Large) for all Designations. If Sterile blades are tested, Non-Sterile blades may also be covered.

**(b) Handle**

Sample of Handle of each Size (Small/Large) from any Designation shall be tested for all requirements to cover each Size (Small/ Large) for all Designations.

2. The Firm shall declare the Varieties of Blades and Handles they intend to cover in the Licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.
3. During the operation of license, it shall be ensured that all varieties covered in the license are tested in rotation, to the extent possible.

**ANNEX B****List of Test Equipment***Major test equipment required to test as per the Indian Standard*

<b>Sl. No.</b>	<b>Tests used in with Clause Reference</b>	<b>Test Equipment</b>
1.	Shape and Dimension as per Cl 5	Micrometre Vernier Calliper (Digital) Profile Projector Bevel protector
2.	Hardness as per Cl 7.1	Vickers Hardness tester
3.	Requirements of sterility as per Cl 8.1	As per IS 10150 :1981.
4.	Visual Examination as per Cl. 9.1	Profile Projector Magnification of 10X
5.	Performance Test as per Cl. 9.2	Piece of chamois leather Steel Scale

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

**ANNEX C**

**Scheme of Inspection and Testing**

**1. LABORATORY** - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

**1.1** The manufacturer shall prepare a calibration plan for the test equipments.

**2. TEST RECORDS** – The manufacturer shall maintain test records for the tests carried out to establish conformity.

**3. LABELLING AND MARKING** – As per the requirement of IS 3319:1995.

**4. CONTROL UNIT** - Blades of same size, material and commercial designation produced in a shift shall constitute a control unit. Handles of same size and commercial designation produced in a shift shall constitute a control unit

**5. LEVELS OF CONTROL** - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

**5.1** All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

**6. REJECTIONS** – 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**

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S: Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
4	Material	4.1 to 4.3	IS 3319	S	One	Each consignment	Stainless steel sheets (IS 6911) used shall be ISI marked. For other materials, no further testing is required if accompanied with test certificate or ISI Marked.
5	Shape and Dimensions	5.1, 5.2, Fig 2, 3, Table 1,2	IS 3319	R	Five	Each Control unit	By actual measurement. In case of failure, marking shall be stopped. The marking shall be resumed only after 10 samples produced consecutively have been found confirming.
6	Workmanship and Finish	6.1 to 6.4	IS 3319	R	Five	Each Control unit	
7	Heat Treatment	7.1	IS 3319	R	Five	Each Control unit	---
9	Visual examination	9.1	IS 3319	R	Each blade		---
	Performance Test	9.2	IS 3319	R	Five	Each Control unit	If any sample fails, blades in that control unit shall not be marked
8	Requirements of sterility	8.1	IS 3319 IS 10150	S	Twenty	Each batch of blades sent for irradiation	---
10	Marking	10	IS 3319	--	Each Blade/Handle and Packages		---
11	Packaging	11	IS 3319	--	Each Blade/Handle and Packages		---

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.