



**PRODUCT MANUAL FOR
SURGICAL INSTRUMENTS - NEEDLES, SUTURE
EYED NEEDLES – SIZES, SHAPES AND DIMENSIONS
ACCORDING TO IS 9165 (Part 2):1992**

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/certificate.

1.	Product	:	IS 9165 (Part 2): 1992
	Title	:	Surgical Instruments, Needles, Suture - Eyed Needles – Sizes, Shapes and Dimensions
	No. of Amendments	:	One
2.	Sampling Guidelines:		
a)	Raw material	:	As per Cl 3.1 of IS 9165 (Part1)
b)	Grouping guidelines	:	Please refer ANNEX – A
c)	Sample Size	:	10 Nos.
3.	List of Test Equipment	:	Please refer ANNEX – B
4.	Scheme of Inspection and Testing	:	Please refer ANNEX – C
5.	Possible tests in a day :		All tests
6.	Scope of the Licence :		
	“Licence is granted to use Standard Mark as per IS 9165 (Part 2)with the following scope:		
	Name of the product		Surgical Instruments - Eyed Suture Needles
	Shape		
	Type of eye		

ANNEX A

Grouping guidelines

1. Eyed Suture Needles as per IS 9165 (Part 2) are categorized as given below:

(a) Shape:

- Straight
- Curved (1/4 Circle)
- Curved (3/8 Circle)
- Curved (1/2 Circle)
- Curved (5/8 Circle)

(b) Type of eye:

- Regular eye
- French spring eye
- Alternate spring eye having a single eye

2. Different shapes of needles and their dimensions are given at Fig. 1 and Table 1 respectively. Further, other combinations of length and diameter as agreed to between the manufacturer and the purchaser may also be permitted.

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

- Needle of any dimension from each shape and type of eye shall be tested to cover needles of all dimensions in the scope of licence for that particular shape and type of eye tested.

4. The Firm shall declare the varieties of needles they intend to cover in the Licence. The Scope of Licence may be restricted based on the manufacturing and testing capabilities of the manufacturer.

5. During 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 Equipment***Major test equipment required to test as per the Indian Standard*

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Size, shapes and Dimensions as per Cl 3	Profile projector, Caliper, micrometer
2.	Hardness as per Cl 5.1 of IS 9165 (Part 1) and IS 1501 (Part1)	Vickers Hardness testing machine
3.	Workmanship and finish as per Cl 6.1 of IS 9165 (Part 1)	Visual Inspection
4.	Burrs and Nicks as per Cl 7.1 of IS 9165 (Part 1)	Profile projector
5.	Corrosion resistance test as per Cl 7.2 of IS 9165 (Part 1)and IS 7531	Test method and equipments as per Cl 3 of IS 7531
6.	Bend test as per Cl 7.3 of IS 9165 (Part 1)	Clamps Leather piece Bevel protractor
7.	Flexibility test (for curved needles) as per Cl 7.4 of IS 9165 (Part 1)	Vernier calliper Measuring scale Profile projector
8.	Sharpness test (except blunt point needle) as per Cl 7.5 of IS 9165 (Part 1)	Aluminium foil Micrometer Load cell Force gauge

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 9165 (Part 2): 1992.

4. CONTROL UNIT – Suture needles of similar type, shape and size, heat treated in a one loading 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				
3.1, 3.2	Size, Shape and Dimensions	3.1 to 3.4, Table 1, Fig.1, Fig. 2, Fig.3	IS 9165 (Part 2)	R	Three	Each Control unit	If more than one sample fails, six samples shall be drawn and tested. In case of any failure, the control unit shall not be marked.
Specification aspects of needles as per IS 9165 (Part 1) : 1992							
3.1	Material	3.1	IS 9165 (Part 1)	S	One	Each consignment	No further testing is required if accompanied with test certificate or ISI marked.
5.	Hardness	5.1	IS 9165 (Part 1)	R	Three	Each Control unit	If more than one sample fails, six more samples shall be drawn and tested. In case of any failure, the control unit shall not be marked.
6.	Workmanship and Finish	6.1 to 6.5	IS 9165(Part 1)	R	Every needle		Individual needles not conforming to the requirement shall not be marked.
7.	Tests						
	Visual	7.1	IS 9165 (Part 1)	R	Every needle		Individual needles not conforming to the requirement shall not be marked.
	Corrosion resistance test	7.2	IS 9165 (Part 1)	R	Three	Each Control unit	If more than one sample fails, six more samples shall be drawn and tested. In case of any failure, the control unit shall not be marked.
	Bend test (for straight needles)	7.3	IS 9165 (Part 1)	R	Three		
	Flexibility test (for curved needles)	7.4	IS 9165 (Part 1)	R	One		
Sharpness test (for all needles except blunt point needles)	7.5	IS 9165 (Part 1)	R	Three			

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.