उत्पाद मैन्यूअल
इंट्रावस्कुलर कैथेटर्स - जीवाणु रहित तथा एक बार प्रयोग में आने वाले कैथेटर्स आईएस/ आईएसओ 10555 (भाग 5): 2013

PRODUCT MANUAL FOR
Intravascular Catheters — Sterile and Single-Use Catheters - Part 5 Over-Needle Peripheral Catheters ACCORDING TO IS/ISO 10555 (Part 5): 2013

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

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/ISO 10555 (Part 5): 2013
	शीर्षक **Title**	:	Intravascular Catheters — Sterile and Single-Use Catheters Part 5 Over-Needle Peripheral Catheters
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	--
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	150 Pcs
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared**	:	• Material • Size of catheters

	in Test Request		
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	All Tests Except Biocompatibility test, Sterilization, Corrosion resistance and Detectability test
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS/ISO 10555 (Part 5): 2013*** with the following scope:

Name of the product	Intravascular Catheters – Sterile and Single-Use Catheters Part 5 Over-Needle Peripheral Catheters
Material	Plastic / Any other (To be declared by the manufacturer)
Nominal outside diameter of catheter tube	0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2.0, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 3.3, 3.4

ANNEX -A

Grouping Guidelines

1. The variety of Intravascular Catheters — Sterile and Single-Use Catheters Part 5 Over-Needle Peripheral Catheters are classified based on the following:

Material	Plastic / Any other (To be declared by the manufacturer)
Nominal outside diameter of catheter tube	0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2.0, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 3.3, 3.4

2. For considering GoL / CSoL, sample of minimum, maximum and any other intermediate nominal outside diameter of cather tube of each type of material shall be tested.

3. The Scope of License may be restricted based on the Manufacturing and testing capabilities of the manufacturer.

4. During the operation of License, it shall be ensured that all the varieties covered in the License are tested in rotation, to the extent possible.

ANNEX- B
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sr No	Tests used in with clause reference	Test equipment
1.	Sterilization (clause 4.3) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- Environmental Chambers (capable of controlling temperature and humidity for accelerated aging) - Sterility Test Equipment (according to ISO 11737) - Visual Inspection Tools (magnification lenses, lighting) - Physical / Mechanical Test Equipment (tensile testers, flow rate setups, pressure testers) - Data Logging Devices (for monitoring temperature and humidity)
2.	Detectability – X-ray (clause 4.5) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- X-ray Imaging System (Digital X-ray or Fluoroscopy), - Radiographic Phantom or Test Jig, Calibration Markers (for X-ray visibility verification)
3.	Detectability – Ultrasound (clause 4.5) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- Ultrasound Scanner (High Frequency Probe), Water Bath / Gel Phantom for simulating tissue
4.	Detectability – MRI (clause 4.5) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- MRI Scanner (1.5T or 3T), MRI Phantom for device placement and visualization
5.	Biocompatibility (clause 4.6) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- Cell culture equipment (incubators, microplate readers), - sterility cabinets, - microscopic examination tools, - Animal testing setups, - adjuvants, and clinical evaluation equipment, - veterinary clinical examination tools, - Pyrogen test equipment (LAL test equipment), - Incubators, Specialized blood interaction test setups, - Spectrophotometers, Coagulation analyzers
6.	Surface finishing (clause 4.7) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- Magnification device (2.5× or higher, e.g., magnifying lens or low-power stereo microscope), - Adequate illumination (white light source), - Angled lighting for detecting surface irregularities, Neutral background surface for inspection.
7.	Corrosion resistance (clause 4.8, Annex A) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- Borosilicate glass beakers for immersion, - Saline solution (0.15 mol/L NaCl) freshly prepared, - Distilled or deionized water,

		- Oven or water bath for heating (capable of reaching boiling point), - Magnification device (to visually inspect corrosion spots), Timer (to measure test durations precisely).
8.	Peak Tensile force (Clause 4.9, Annex B, table-1) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- Universal tensile testing machine, - Load cell with suitable range and precision, - Grips / clamps designed for tubing and hubs, - Temperature-controlled water bath (37 ± 2 °C) for pre-conditioning (for hydratable catheters), - Ruler / caliper for measuring gauge length and OD, Timer for conditioning and recording results
9.	Freedom from leakage during pressurization – Liquid leakage (clause 4.10, Annex C) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	-Pump or pressure-generating device (capable of ≥300 kPa) - Pressure gauge or sensor - Leak-proof connectors - Occluding clamps for catheter end - Distilled or deionized water - Timer for recording the test duration
10.	Freedom from leakage during pressurization – Air Leakage (clause 4.10, Annex I) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- Pump or pressure-generating device (capable of ≥300 kPa) - Leak-proof connectors - Occluding clamps - Water bath (22 ± 5 °C) for visual detection of air bubbles - Timer for recording test duration
11.	Freedom from leakage during aspiration (clause 4.11, Annex D) IS 18292 (PART 1): 2024 ISO 10555-1: 2023	- 10 mL syringe compliant with ISO 7886-1. - De-aerated distilled or deionized water. - Occluding clamps (to block the catheter end). - Timer (±1 s).
12.	Hubs (clause 4.12) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Reference Luer Fittings (compliant with ISO 80369-6 or 80369-7) - Torque Test Gauge (to assess fit and secure locking) - Micrometer / Calipers (to measure dimensions and tolerances) - Pressure Pump (to verify leak-free connections) - Occluding Clamps (to isolate sections) - Timer (for pressure maintenance) - Magnification device (to inspect threads and surfaces)
13.	Flowrate (clause 4.13, Annex E) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Constant-level tank (1 m water column) - Luer fitting (to attach the catheter) - Graduated cylinder or precision balance (±1%) - Stopwatch / Timer (±1 s) - Flowmeter (optional, ±5%) - Distilled or deionized water (22 ± 5 °C)

14.	Power injection burst pressure (clause 4.14, Annex F & Annex G) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Pump / Pressure Source (capable of achieving the rated pressure for the catheter) - High-accuracy pressure sensor or gauge (±5%) - Reservoir containing test fluid (fluid with a known, relevant viscosity) - Occluding clamps / fittings (to secure the catheter) - Temperature-controlled water bath (37 ± 2 °C) - Timer / stopwatch (±1 s) - Data Acquisition System (optional) for recording pressure data
15.	Packaging System (clause 4.15) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Sterility Testing Setup (incubators, sterility test isolators) - Seal Strength Tester (tensile tester for peel test) - Burst or Pressure Tester for packaging integrity - Environmental Chambers (for accelerated aging studies) - Drop Test / Vibration Test Equipment (for transportation testing per ISO 11607, ASTM D4169) - Visual Inspection Tools (magnification lens, lighting)
16.	Simulated Use Test (clause 4.16) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Anatomical vascular model or simulated clinical pathway (made of silicone or plastic) - Pump or flow circuit (for fluid dynamics) - Guidewires and introducers (as applicable) - Torque meter or sensor
17.	Kink Resistance Test (clause 4.16) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Mandrels of defined diameter or bending fixtures - Force measurement device (for bending resistance) - Visual inspection tools (magnification lens, camera)
18.	Torque Resistance Test (clause 4.16) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Torque testing device / torsion tester - Angular displacement measurement tool (digital angle meter) - Clamps or holders for catheter ends
19.	Coating Integrity Testing (clause 4.17) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Friction Test System (e.g., catheter simulated insertion rig) - Push-Pull Tester / Linear Motor - Microscopic examination equipment (optical or electron microscope) - Magnification lens or camera for surface inspection
20.	Particulate Testing (clause 4.17) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Particle counting equipment (Light Obscuration Particle Counter) - Inert test fluid (e.g., distilled or deionized water) - Filtration assembly and membrane filters (for gravimetric or microscopic particle collection) - Gravimetric balance (accuracy ±1 µg) - Microscope (for visual particle examination)
21.	Distal tip stiffness testing to consider for neurovascular applications (clause 4.18, Annex K) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Stiffness Test Fixture (to hold catheter in position) - Force Sensor / Load Cell (high-sensitivity, e.g., mN range) - Displacement Actuator (capable of precision bending) - Clamps (to fix the catheter segment)

		- Data Acquisition System (to record force vs displacement) - Micrometer or Linear Scale (to measure displacement and exposed length)
22.	Nominal outside diameter (clause 5.1) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Precision Micrometer or Optical Measuring Device (accuracy to ±0.001 mm) - Vernier Calipers - Mandrels / Gauge Blocks (for verifying measurement device calibration) - Magnification Devices (optional) for fine inspection
23.	Nominal inside diameter (clause 5.2) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Pin Gauge Set (precision ground) - Small Bore Plug Gauges for verifying internal diameter - Vernier Caliper - Micrometer or Optical Micrometer (±0.001 mm) - Magnification Devices (for inspection) - Flowmeter / Pressure Testing Apparatus (optional for indirect verification)
24.	Nominal Effective length (clause 5.3) IS 18292 (Part-1): 2024 ISO 10555-1:2023	- Precision measuring scale or steel ruler (±1 mm) - Measuring tape (±1 mm) for longer catheters - Flat inspection surface -Vernier Caliper - Clamps / holders (to fix catheter straight) - Magnification device (optional) for checking endpoints precisely
25.	Colour code (clause 4.3.1) IS/ISO 10555-5:2013	- Magnification device (2.5×) (optional) - Adequate lighting (natural or standardized illumination) - Color reference chart (according to ISO 6009)
26.	Catheter Unit (Clause 4.3.2) IS/ISO 10555-5:2013	- Precision calipers (±0.01 mm) - Micrometer (±0.001 mm) for external diameter verification - Pin gauges for internal diameter checking - Measuring tape / scale (±1 mm) for length measurement - Magnification device (2.5x or higher) - Adequate lighting - Visual inspection setup - Straightedge / flat surface for checking straightness - Mandrels / guides (as required)
27.	Needle Point (clause 4.3.3.2) IS/ISO 10555-5:2013	- Magnification device (at least 2.5×) - Adequate lighting / inspection lamp - Simulated insertion materials (e.g., synthetic skin, silicone pads) - Push-testing rig / force sensor (to measure penetration force) - Magnification device / stereo microscope - Protractor or optical angle measuring device (for verifying bevel angle)

28.	Needle Hub (Clause 4.3.3.3) (IS/ISO 10555-5: 2013)	- Magnification device (2.5× or higher) - Precision calipers or optical micrometer (±0.01 mm) - Tensile testing machine (capable of applying forces per standard) - Clamps or fixtures for holding the hub and needle assembly -
29.	Strength of union between needle hub and needle tube (clause 4.3.3.4) IS/ISO 10555-5:2013	- Universal tensile testing machine - Appropriate clamps / fixtures (to securely hold both the needle hub and the needle tube) - Measurement device for recording tensile load (±1%) - Conditioning chamber (22 ± 2 °C, 40–60% RH) for pre-conditioning samples, if required
30.	Venting fitting test (clause 4.3.4 Annex D) (IS/ISO 10555-5: 2013)	- Constant-level tank (~400 ± 20 mm head) - Delivery tube (internal diameter ≥3 mm) - Clamp / Valve for flow control - Puncturable membrane (e.g., latex cap) - Stopwatch / Timer (±1 s) - Test fluid: Saline (9 g/L) and Glycerol solution (450 mL) mixed with saline (550 mL) as per the method.

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 subcontracting/sharing 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: *Intravascular Over-Needle Peripheral Catheters of same size manufactured in a day under similar process condition from the same consignment of raw materials* shall 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.

2. ENSURING COMPLIANCE THROUGH TESTING - manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard. 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 recognised/empanelled laboratories, or

   b. Any accredited laboratory as per ISO/IEC 17025

2.1 TEST RECORDS- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be marked legibly and indelibly on the packaging of *Intravascular Over-Needle Peripheral Catheters* provided always that the cathers so marked conforms to each requirement of the specification.

3.1 Marking on the packaging of *Intravascular Over-Needle Peripheral Catheters* shall be done as per Cl. 4.4 of IS/ISO 10555 (Part 5): 2013.

3.2 **Additional Marking requirements**: The following additional requirement shall also be marked on the packaging of the *Intravascular Over-Needle Peripheral Catheters*:

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

3.3 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

4. HYGIENIC CONDITIONS (if applicable) – NA.

5. REJECTION - 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)		
Test Details				**Levels of Control**		
Cl.	**Requirement**	**Test Method**		**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**			
4	Requirements		IS/ISO 10555-5			
	Sterilization	4.3	IS 18292 (Part 1): 2024 ISO 10555-1 : 2023	One	Once in a month	
	Detectability	4.5		One	Once in a month	
	Biocompatibility	4.6	IS 18292 (Part 1): 2024 ISO 10555-1: 2023 & ISO 10993-1	One	Once in every three year	Whenever there is a change in raw materials, testing is to be carried out
	Surface	4.7	IS 18292 (Part 1): 2024 ISO 10555-1 : 2023	Firm to have adequate in-process controls to check compliance of this parameter as per the tolerances given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
	Corrosion resistance	4.8 & Annex A		One	Once in a month	
	Peak tensile force	4.9 & Annex A		One	Each Control Unit	
	Freedom from leakage during pressurization	4.10 & Annex C		One	Each Control Unit	
	Freedom from leakage during aspiration	4.11 & Annex D		One	Each Control Unit	
	Flowrate	4.13 & Annex E		One	Each Control Unit	
	Power injection burst pressure	4.14 & Annex F Annex G		One	Once in a month	
	Packaging system		ISO 11607-1	One	Each Control Unit	
4.2	Multilumen catheters	4.2	IS/ISO 10555-5	Firm to have adequate in-process controls to check compliance of this parameter as per the tolerances given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		

4.3	Physical requirements					
4.3.1	Colour code	4.3.1 Table 1	IS/ISO 10555-5	Firm to have adequate in-process controls to check compliance of this parameter as per the tolerances given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
4.3.2	Catheter unit	4.3.2	IS/ISO 10555-5			
4.3.3	Needle – Material	4.3.3.1		One	Each Consignment of raw material	No further testing is required if accompanied with TC or ISI marked
	Needle point	4.3.3.2	IS/ISO 10555-5	One	Each Control Unit	
	Needle hub	4.3.3.3	IS/ISO 10555-5	One	Each Control Unit	
	Strength of union between needle hub and needle tube	4.3.3.4 Annex - A	IS/ISO 10555-5	One	Each Control Unit	
4.3.4	Vent fitting	4.3.4 Annex – D	IS/ISO 10555-5	One	Each Control Unit	