आई एस 10654: 2018 / आईएसओ 7864: 2016 - 'निर्ज़र्म अधोत्वचिय एक बार उपयोग की जाने वाली सुइयां – आवशाकताएं और परीक्षण के तरीक़े' के अनुसर उत्पाद मैन्युअल

PRODUCT MANUAL FOR Sterile Hypodermic Needles for Single Use — Requirements and Test Methods as per IS 10654: 2018 / ISO 7864: 2016

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 10654: 2018 / ISO 7864: 2016
	शीर्षक **Title**	:	Sterile Hypodermic Needles for Single Use — Requirements and Test Methods
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	NA
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	100 Pcs
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**	:	• Designated metric size of the needle tube (OR) OD (tip) / OD (hub) • Type of needle • Material • Wall thickness of the needle

			• Sharp injury protection • Nominal length of needle tube
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
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS 10654: 2018 / ISO 7864: 2016*** with the following scope:

Name of the product	Sterile Hypodermic Needles for Single Use — Requirements and Test Methods
Designated metric size of the needle tube	
(*OR*) **OD (tip) / OD (hub)**	
Type of needle	Tubular/ Taper
Material	Plastic / Other Material (to be specified by the manufacturer)
Wall thickness of the needle	RW (regular wall) / TW (thin wall) / ETW (extra thin wall) / UTW (ultra-thin wall)
Sharp injury protection	With / Without
Nominal length of needle tube	(to be declared by the manufacturer)

ANNEX -A
Grouping Guidelines

1. Sterile Hypodermic Needles for Single Use — Requirements and Test Methods as per IS 10654: 2018 / ISO 7864: 2016 may be classified as below:

Designated metric size of the needle tube	
(AND / OR) **OD (tip) / OD (hub)**	
Type of needle	Tubular/ Taper
Material	Plastic / Other Material (to be specified by the manufacturer)
Wall thickness of the needle	RW (regular wall) / TW (thin wall) / ETW (extra thin wall) / UTW (ultra-thin wall)
Sharp injury protection	With / Without
Nominal length of needle tube	(to be declared by the manufacturer)

2. For considering GoL / CSoL, Sterile Hypodermic Needles of maximum and minimum designated metric size of needle tube (or maximum OD (tip) / OD (hub)) of any nominal length for each type of needle, and for each type of material and wall thickness of the needle shall be tested.

3. However, the following relaxation may be considered:

    i. If needles of with sharp injury protection is tested, needles without sharp injury protection may be covered under the scope of the licence.

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

5. 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)

S.No.	Tests used in with Clause Reference	Test Equipments
1.	Tolerances on Diameter and Length (Cl. 5.3)	Coordinate Measuring Machine Optical Comparator Size or Taper Gauge Roundness Tester Length Gauge
2.	Edge Spacing (Cl. 5.4)	Computerized Profile Gauge
3.	Material (Cl. 6)	Spectrometer (OES)
4.	Hardness (Cl. 7)	Rockwell Hardness Tester
5.	Surface Roughness for Lateral Surface (Cl. 10.1)	Computerized Profile Gauge
6.	Surface Roughness for End Face (Cl. 10.2)	Computerized Profile Gauge
7.	Axial Runout (Cl. 10.3)	End Run-out Gauge

ANNEX C
SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1. It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan 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 defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same 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: *Sterile Hypodermic Needles of same type and same designated metric size of needle tube having same wall thickness manufactured in a day under similar process condition from the same consignment of raw* 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 incorporated legibly and indelibly on the packaging of the Sterile Hypodermic Needles provided always that the Sterile Hypodermic Needles so marked conforms to each requirement of the specification.

3.1 Marking shall be done as per Cl. 6 of IS 10654: 2018 / ISO 7864: 2016.

3.2 **Additional Marking requirements**: The Sterile Hypodermic Needles shall also be marked with the following additional requirement on its packaging:

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 Methods**		**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**			
4.3	Cleanliness	4.3	IS 10654	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.		
4.4	Limits for acidity or alkalinity	4.4 & Annex A	IS 10654	25 pcs	Each Control Unit	
4.5	Limits for extractable metals	4.5 & Annex A	IS 10654	25 pcs	Each Control Unit	
4.7	Color Coding	4.7	IS 10654	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.		
4.8	Needle Hub					
4.8.1	Conical fitting		ISO 80369-1, ISO 594-1 & ISO 594-4	One	Once in every six month	
4.9	Needle Cap	4.9	IS 10654	One	Once in every six month	
4.10	Needle tube					
4.10.1	General	4.10.1	IS 10654	One	Once in every six month	
4.10.2	Tolerance on length	4.10.2 & Table 1	IS 10654	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.		
4.10.3	Freedom From defect	4.10.3	IS 10654			
4.10.4	Lubricant	4.10.4	IS 10654	One	Once in every six month	
4.11	Needle Point	4.11, Annex B &	IS 10654	One	Once in every six month	

		Annex A				
4.12	Bond between hub and needle tube	4.12& Table 2	IS 10654	One	Once in every six month	
4.13	Patency of lumen	4.13, & Table 3 & Annex C	IS 10654	One	Once in every six month	
4.14	Sharps injury protection		ISO 23908	One	Once in every six month	
4.15	Sterility and biocompatibility					
4.15.1	Sterility	4.15.1	IS 10654	One	Once in every six month	
4.15.2	Biocompatibility		ISO 10993-1	One	Once in every three years	Whenever there is any change in the source or in the specification of the materials, testing is to be carried out.