उत्पाद मैन्युअल
आईएस 10258 (भाग 1): 2022 के अनुसार
एकल उपयोग के लिए स्टेराइल हाइपोडर्मिक सीरिंज
भाग 1 मैन्युअल उपयोग के लिए सीरिंज
दस्तावेज़ संख्या – पीएम/आईएस 10258 (भाग 1)/3/ दिसंबर /2023

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिशिता की सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसी द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस प्रमाणीकरण लाइसेंस/ प्रमाणपत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है ।

PRODUCT MANUAL FOR
Sterile Hypodermic Syringes for Single Use
Part 1 Syringes for Manual Use
According to IS 10258 (Part 1): 2022
Document No. - PM/IS 10258 (Part 1)/3/December 2023

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.

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PRODUCT MANUAL FOR STERILE HYPODERMIC SYRINGES FOR SINGLE USE ACCORDING TO IS 10258 (Part 1): 2022/ISO 7886-1:2017

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 10258 (Part 1): 2022/ISO 7886-1:2017
	Title	:	Sterile Hypodermic Syringes for Single Use Part 1 - Syringes for Manual Use
	No. of Amendments	:	NIL
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	-
b)	**Grouping guidelines**	:	Please refer ANNEX – A
c)	**Sample Size**	:	100 Syringes
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 10258 (Part 1): 2022/ISO 7886-1:2017 with the following scope:		
	Name of the product		Sterile Hypodermic Syringes for Single Use Part 1 -Syringes for Manual Use
	Nominal Capacity (in ml)		
	Requirement of Needle		With / without needle
	Material		Plastic / Other Material (to be specified by the manufacturer)

ANNEX A

Grouping Guidelines

1. Sterile Hypodermic Syringes for Single Use Part 1 -Syringes for Manual Use are classified base as per IS 10258 (Part 1): 2022/ISO 7886-1:2017 are classified based on the following:

   i. With / without needle

   ii. Construction material (Plastic / others)

   iii. Nominal Capacity as tabled below:

Group	I	II	III	IV	V	VI	VII
Nominal Capacity of Syringe, V (ml)	$V < 2$	$2 \leq V < 5$	$5 \leq V < 10$	$10 \leq V < 20$	$20 \leq V < 30$	$30 \leq V < 50$	$V \geq 50$

2. For considering GoL / CSoL, Syringes of each type of construction material of any nominal capacity from each group of nominal capacity shall be tested to cover all other nominal capacity for that particular type of construction material.

3. If syringes with needle has been tested, syringes without needle may be considered.

4. Firm shall declare the varieties (including nominal capacity) of syringes intended to cover in Scope of the Licence. 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.

Note: The firm shall declare the type of lubricant to be used in the Syringes and conformity for the same needs to be submitted the firm.

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.	Limits for acidity and alkalinity (Clause 6)	pH meter, Distilled/Deionized water, Borosilicate glassware
2.	Limits for extractable metals (Clause 7)	Atomic Absorption spectrophotometer, Distilled / Deionized water, Borosilicate glassware
3.	Lubricants (Clause 7) (For quantity of Silicone)	Silicone oil, 4-methyl- 2-pentanon, Measuring flask, Transfer pipette, Atomic absorption spectrophotometer, analytical balance
4.	Graduated Scale (Clause 9) Barrel Dimensions (Clause 10.1) Plunger stopper/plunger assembly (Clause 11), Nozzle lumen (Clause 12.3)	Vernier caliper, Digital Micrometer
5.	Barrel flanges (Clause 10.2)	Inclined surface
6.	Dead space (Clause 13.1,Annex C)	Apparatus and Reagents as per Annex C of IS 10258 (Part 1)
7.	Freedom from air leakage past piston(Clause 14.2 – Annex B)	Apparatus and Reagents as per Annex B of IS 10258 (Part 1)
8.	Freedom from liquid leakage past piston(Clause 14.2 – Annex D)	Apparatus and Reagents as per Annex D of IS 10258 (Part 1)
9.	Force to operate the Piston	Apparatus and Reagents as per Annex E of IS 10258 (Part 1)

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 equipment.

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

3. LABELLING AND MARKING – Sterile Hypodermic Syringes for Single Use Part 1 - Syringes for Manual Use shall be marked as per Cl. 15.2 & 15.3 of IS 10258 (Part 1): 2002. The packaging of the Sterile Hypodermic Syringes for Single Use Part 1 -Syringes for Manual Use shall be done as per Cl. 15.4 to Cl. 15.6 of IS 10258 (Part 1): 2022.The Standard Mark as given in the Schedule of the licence shall be either printed or stenciled on the Syringes.

3.1 In addition to the above, the licence no. CM/L-_____ and details of BIS website shall be marked on the packaging of the syringe as follows: "For details of BIS certification please visit www.bis.gov.in"

4. CONTROL UNIT – Syringes of same nominal capacity manufactured from the same type of construction material in a day 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 Standard 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**		
Clause	**Requirement**	**Test Methods**			**No. of Sample**	**Frequency**	**Remarks**
		Clause & Table / Annex	**Reference**				
5	General requirements	5	IS 10258 (Part 1)	R	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		
6	**Extraneous matter**						
6.1	General	6.1	IS 10258 (Part 1)	R	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		
6.2	Limits for acidity or alkalinity	6.2 & Annex – A	IS 10258 (Part 1)	R	3	Each Control Unit	
6.3	Limits for extractable metals	6.2 & Annex – A	IS 10258 (Part 1)	R	3	Each Control Unit	
7	Lubricant	7 & Annex F (for Silicone Oil)	IS 10258 (Part 1)	R	3	Each Control Unit	
8	Tolerance on graduated capacity	8 & Table 1	IS 10258 (Part 1)	R	1	Each Control unit	
9	**Graduated Scale**						
9.1	Graduated Scale	9.1 & Table 1	IS 10258 (Part 1)	R	1	Each Control unit	
9.2	Numbering of scales	9.2 & Table 1	--do--	R	1		

9.3	Overall length of scale to nominal capacity line	9.3 & Table 1	--do--	R	1		
9.4	Position of scale	9.3 & Table 1	--do--	R	1		
10	**Barrel**						
10.1	Dimensions	10.1	IS 10258 (Part 1)	R	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		
10.2	Barrel flanges	10.2	IS 10258 (Part 1)	R			
11	**Plunger stopper/plunger assembly**						
11.1	Design	11.1, Annex B & Figure 3	IS 10258 (Part 1)	R	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		
12	**Nozzle**						
12.1	Conical fitting		ISO 80369-7	R	1	Each Control unit	
12.2	Position of nozzle on end of barrel	12.2	IS 10258 (Part 1)	R	1	Each Control unit	
12.3	Nozzle lumen	12.3	IS 10258 (Part 1)	R	1	Each Control unit	
13	**Performance**						
13.1	Dead space	13.1, Annex C & Table 1	IS 10258 (Part 1)	R	1	Each Control unit	
13.2	Freedom from air and liquid leakage past plunger stopper	Annex B & Annex D	--do--	R	1	Each Control unit	
13.3	Force to operate the piston	Annex E	--do--		1	Each Control unit	

13.4	Fit of plunger stopper/plunger in barrel	13.4	--do--	R	1	Each Control unit	
14	**Packaging**						
14.1	Unit packaging and self-contained syringe units	14.1.1 14.1.2	IS 10258 (Part 1)	R	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		
14.2	Multiple unit pack	14.2	--do--	R			
14.3	User packaging	14.3	--do--	R			
15	**Information supplied by the manufacturer**						
15.1	General	15.1	IS 10258 (Part 1)	R	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		
15.2	Syringes	15.2.1 15.2.2	--do--	R			
15.3	Unit packaging	15.3	--do--	R			
15.4	Multiple unit packs	15.4.1 15.4.2	--do--	R			
15.5	User packaging	15.5	--do--	R			
15.6	Storage container	15.6	--do--	R			
15.7	Transport wrapping	15.6 15.7	--do--	R			

Note-1: The Control unit and the levels of control as decided by the Bureau are obligatory, to which the licensee shall comply with.
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.