

# PRODUCT MANUAL FOR CLINICAL THERMOMETERS – ENCLOSED SCALE TYPE ACCORDING TO IS 3055 (Part 2): 2004

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	Due June 4 . IS 2055 (Deept 2) + 2004					
1.	Product	,				
	Title	:	Clinical Thermometers – Enclosed Scale Type			
	No. of Amendments	:	NIL			
2.	Sampling Guidelines:					
a)	Raw material	:	-			
b)	Grouping guidelines		Not Applicable. Standard covers single type only.			
c)	Sample Size	:	10 pieces			
3.	List of Test Equipment	:	Please refer <u>ANNEX – A</u> .			
4.	Scheme of Inspection and Testing	:	Please refer <u>ANNEX – B</u> .			
5.	Possible tests in a day:					
	<ul> <li>(i) Construction as per Cl. 7.3</li> <li>(ii) Dimensions as per Cl. 7.4</li> <li>(iii) Graduation and numbering as per Cl. 7.5</li> <li>(iv) Appearance as per Cl. 8.1</li> <li>(v) Influence of immersion time as per Cl. 8.3</li> </ul>					
6.	Scope of the Licence :					
	"Licence is granted to use Standard Mark as per IS 3055 (Part 2): 2004 with the following scope:					
	Name of the product	product   Clinical Thermometers				
	Туре	Enclosed Scale, Mercury-in-glass type				
	Range					

## ANNEX A

# **List Of Test Equipment**

Major test equipment essentially required to test as per the Indian Standard

S. No.	Tests used in with Clause Reference	Test Equipment
	Materials- glass tubing as per	<ul><li>a) Special test thermometers</li><li>b) Temperature controlled test bath (liquid bath or</li></ul>
1.	Cl. 7.2.1	metal block type oven)
		c) Ice bath
		a) Standard Lab chemicals and apparatus
		b) Ball mill
	Materials- hydrolytic resistance	c) Sieving-machine
2.	of glass as per Cl. 7.2.2	d) Ultrasonic cleaner
	of glass as per Cl. 7.2.2	e) Drying Oven
		f) Thermometer
		g) Heating Bath
	Hardness of maximum	a) Centrifuge
3.	indicating device as per	b) Stopwatch
	C1. 7.3.2.1	c) Temperature controlled water bath
4	D: : Cl 7.4	a) Vernier Callipers
4.	Dimension as per Cl. 7.4	b) Micrometer
_	Ageing and Accuracy as per	a) Temperature controlled water bath
5.	Cl. 8.2	b) Reference Thermometer
	Influence of immension time as non	a) Temperature controlled water bath
6.	Influence of immersion time as per C1. 8.3	b) Stopwatch
	Ci. 0.3	c) Reference Thermometer

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

#### ANNEX B

### **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** As per the requirements of IS 3055 (Part 2): 2004.
- **4. CONTROL UNIT** All the clinical thermometers manufactured in a day shall constitute a control unit.
- **5. LEVELS OF CONTROL** The tests as indicated in column 1 of <u>Table 1</u> and the levels of control in column 3 of <u>Table 1</u>, 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.
- **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. Glass piece of rejected thermometers may be scrapped after recovering the mercury.

# TABLE 1

(1)				(2)			
Test Details				Test equipment	Le		
Cl.	Requirement	Test Methods Clause Reference		R: required (or) S: Sub- contracting permitted	No. of Sample	Frequency	Remarks
	Materials						
7.2	Glass tubing	7.2.1		S	Every consignment received		#
	Glass	7.2.2	IS 3055 (Pt 2)	S	One from every batch of glass used for maximum device, capillary tube & bulb received.		#
	Thermometric liquid	7.2.3		-	-		Test certificate from supplier
7.3	Construction	7.3.1- 7.3.6	IS 3055 (Pt 2)	R	Each thermometer		
7.4	Dimensions	7.4 & Table 1	IS 3055 (Pt 2)	R	Each thermometer		
7.5	Graduation and Numbering	7.5.1- 7.5.8	IS 3055 (Pt 2)	R	Each thermometer		
8.1	Appearance	8.1	IS 3055 (Pt 2)	R	1% with min. 5 thermometers	Each control unit	
8.2	Ageing and Accuracy	8.2	IS 3055 (Pt 2)	R	1% with min. 5 thermometers	Each control unit	

(1)				(2)	(3)		
Test Details				Test equipment	Levels of Control		
Cl.	Requirement Test Method		t Methods	requirement	No. of Sample	Frequency	Remarks
		Clause	Reference	R: required (or) S: Sub- contracting permitted			
8.3	Influence of immersion time	8.3	IS 3055 (Pt 2)	R	1% with min. 5 thermometers	Each control unit	

<sup>#</sup> No further testing is required if consignment/ batch is accompanied with a Test Certificate from supplier.

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

Note-2: The control unit and levels of control as decided by the Bureau are obligatory to which the licensee shall comply with.