

# First Sensitisation Meeting

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**Dealing Officer  
with a New Licensee**

# Planning by the DO

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- **Time for Discussion - Convenient to Both (May be physical or through VC)**
- **Self Preparation on the agenda (Study of the ISS/PM/Relevant Circulars)**
- **Keeping relevant handouts ready (For easy dissemination of pertinent information)**

# Dealing officer - Things to Bear in Mind

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- DO is representing BIS - polite but firm .
- Licensee is representing another organization and not a subordinate .
- Licensee is new to BIS - likely to be less informed about BIS , guidelines , responsibilities and duties .
- At the same time, licensee is likely to be more informed about the intricacies of the product segment. He just needs a Positive Attitude and effective Hand Holding.
- Maintain time – don't keep visitor waiting unnecessarily.
- Be courteous.
- Patient listener –Don't appear uninterested.
- Understand the product and its manufacturing process and the associated issues.



# Dissemination of Information

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- Use simple language -He might not be familiar with our terminologies.
- Be specific – don't confuse him with irrelevant information.
- Give complete information on relevant documents like SIT , PM , correcting misconceptions - Dos and Don'ts
- Educate him about the Sources of Information ( website etc ) and how to access the same.
- Disseminate and emphasize on positive information first.
- Guide him to Manakonline and the BIS Website for relevant information.

# DETAILED INFORMATION

for










# NEW LICENSEES



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- BIS WARMLY WELCOMES YOU AS ONE OF THE MEMBERS OF FAST GROWING FAMILY OF OVER 40000 BIS LICENSEES
  - BIS EXPECTS YOU TO FOLLOW THE QUALITY PATH CHOSEN IN TRUE LETTER AND SPIRIT
  - WE LOOK FORWARD TO A LONG LASTING ASSOCIATION WITH YOUR ORGANIZATION AND ALSO ASSURE YOU OF COMMITTED SUPPORT IN ADDRESSING ALL YOUR QUALITY CONCERNS THROUGH OUR WIDE GAMUT OF CONFORMITY ASSESMENT SERVICES



# Things to do by the Licensee

1. Read the Conditions of the licence 
2. Use BIS mark only on - conforming products, varieties covered in licence. 
3. Design of Standard mark on product to be as specified 
4. Please read the product manual 
5. Pl read the Scheme of testing and Inspection ( SIT ) and ensure compliance 
6. Be familiar with manakonline - open manakonline portal at least once daily 
7. Assistance to BIS Officers or BIS Authorized Agents during Inspection ( samples , records etc ). 
8. Apply inclusion through manakonline ( generate QR code through LIMS ) 
9. Inclusion sample – Generate Test Request through LIMS . Send sample to BIS approved lab 
10. Inform BIS - change in the QC personnel , mfg process, testing or manufacturing machinery or relocation.
11. Self SUS - relocation of the manufacturing unit or major manufacturing machinery.
12. Repair , replace ISI marked product if complaint is established.
13. Read all guidelines - ( <https://bis.gov.in/index.php/product-certification/product-certification-process/> )

# DON'Ts – DO to Inform the Licensee

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## Don't use the BIS Standard Mark in the following cases

- Non-conforming or on varieties not in the scope of licence.
- Any other material or product other than the product for which licence has been granted by BIS.
- Without completion of testing of the batch as per SIT.
- During deferment / suspension / expiry / cancellation.
- In case of relocation to the new premises till receipt of ROS from BIS.



# YOUR FEEDBACK MATTERS

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- Always feel free to share any problems faced / facing wrt the activities of BIS. Your inputs are valuable to us.
- BIS looks forward to an everlasting association with your organization and also assures you of committed support in addressing all your quality concerns through our wide gamut of conformity assessment services
- Your organization can further enhance your quality profile by adopting the various Management Systems Conformity Assessment Schemes ( Pl copy and paste the link on browser to know more )

<https://bis.gov.in/index.php/system-certification-overview/certification-process/systems-under-certification/>

- We would also like to know the Source of motivation for your organization for going for BIS Licence. This information is valuable to us.

Thank you

# IMPORTANT CONDITIONS OF THE LICENCE

- **DESIGN OF ISI MARK** - shall be identical as given in the licence. The photographic enlargement or reduction of the Standard Mark may also be used, unless otherwise specified by the Bureau.
- **RESPONSIBILITY OF CONFORMITY OF GOODS** – Responsibility lies with licensee . Do not use the Standard Mark on non –conforming products and / or outside the scope of the licence.
- **RECALL OF NON CONFORMING PRODUCTS** - Bureau may direct the licensee or his representative to recall the non-conforming goods and articles.
- **RESTRICTIONS ON USING ISI MARK** – During deferment, suspension and after expiry
- **COMPLIANCE TO SCHEME** – Follow requirements of SIT ( testing frequency , sampling , marking ), Indian Standard ( tests , criteria for conformity, method of testing ), including labelling & marking requirements.
- **MAINTAIN RECORD** – For tests specified in SIT , Raw materials , production dispatch, calibration etc
- **SURVEILLANCE INSPECTIONS** - Provide all assistance in connection with carrying out inspection
- **INFORMATION TO BIS** – Details of production , list of consignees, distributors, dealers or retailers.
- **NO TRANSFER OF LICENCE** - licence shall not be transferred to any person without approval of BIS.
- **COMPLAINTS** - If established, Repair or Replace the ISI marked product. Compensation

**VIOLATION OF CONDITIONS OF LICENCE LEADS TO CANCELLATION**

Detailed conditions of licence  
Regulation 6 of BIS ( Conformity Assessment) Regulations 2018- Page 234

Link given below – go to page 234 – Regulation 6

[https://bis.gov.in/wp-content/uploads/2019/03/BIS\\_CA\\_12032019.pdf](https://bis.gov.in/wp-content/uploads/2019/03/BIS_CA_12032019.pdf)



# SCOPE OF THE LICENCE

Licence document is generated after grant of licence and will be available in manakonline. To be retained for all future purpose and is to be referred in all correspondences

The name mentioned is holder of the licence – Any change in name is to be informed to BIS alongwith supporting documents

Licence is given for the premises mentioned in factory address. Any change in address is to be informed to BIS prior to shifting

Licence is valid only for the product mentioned under column 2 . For other products pl obtain separate licence

Licence is valid only for the varieties mentioned under column 3 of the table. For other varieties pl apply for inclusion before using ISI mark on those

Marking fee mentioned under column 4 is payable by the licence as per the rates prescribed therein

Licence is valid only upto the period mentioned . Apply for renewal at least 2 months prior to the end of validity period.

Do not use ISI mark after validity is over , during deferment, suspension or after expiry of licence


Schedule

(Licence No.CM/L-.....)

Name:

Factory Address:

Validity from ..... to.....

Standard Mark	Indian Standard	Scope of Licence	Marking Fee
(1)	(2)	(3)	(4)
ISI 			₹ ____ per unit for the first ____ units, ₹ ____ per unit for the rest of the units with a minimum marking fee of ₹ ____ /- during an operative period of one year  Unit - ____  Minimum marking fee for one operative year payable in advance which will be carried over to next renewal(s)

Signed, Sealed and Dated this ..... day of ..... month of Year.....

for Bureau of Indian Standards

## Design of the Standard Mark

Standard mark to be as per specified dimensions. Photographic enlargement allowed unless otherwise specified by BIS

**Pl see BIS ( Conformity  
Assessment) Regulations 2018  
Page 275**

Link given below  
(go to page 275)

[https://bis.gov.in/wp-content/uploads/2019/03/BIS CA 12032019.pdf](https://bis.gov.in/wp-content/uploads/2019/03/BIS_CA_12032019.pdf)

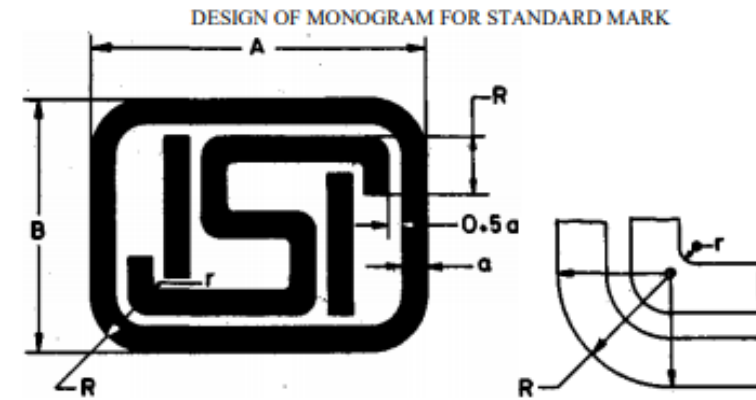


Figure 1 MONOGRAM FOR STANDARD MARK

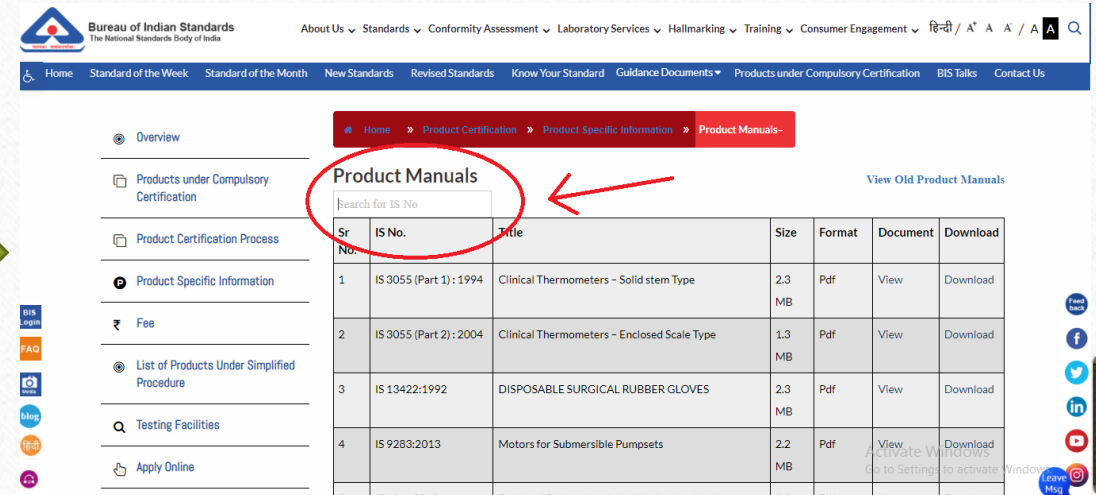
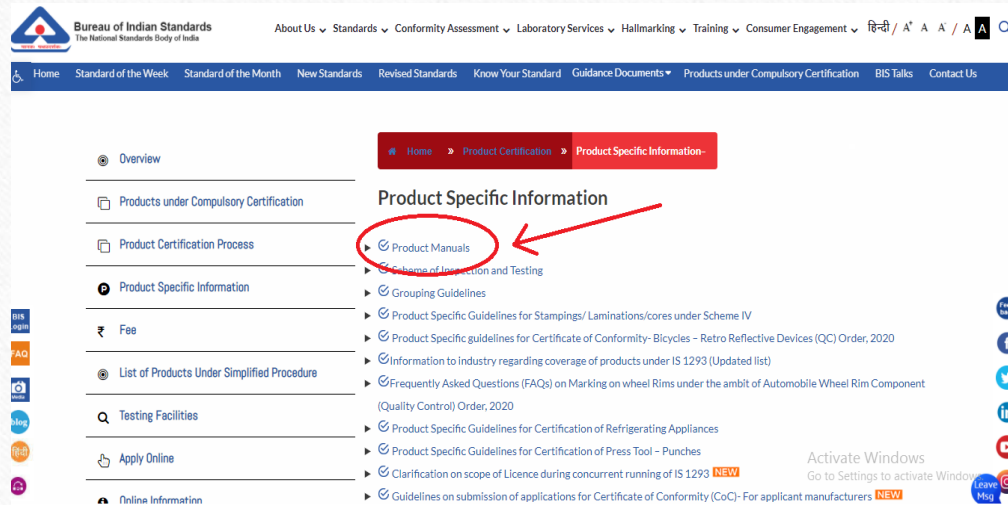
The monogram of the Standard Mark consists of the pictorial representation, drawn in the exact style as indicated in Figure 1 and in relative proportions as given in Table 1.

Table 1 Preferred Dimensions of Monogram  
All dimensions in millimeters

A	B	a	R	r	SIZE OF LETTERS
2.5	1.9	0.2	0.4	-	1.0 mm
5	3.8	0.4	0.8	0.1	1.0 mm
10	7.5	0.7	1.7	0.2	2.0 mm
20	15	1.5	3.3	0.5	3.0 mm
40	30	2.9	6.7	1.0	4.0 mm
80	60	5.9	13.4	1.9	6.0 mm
160	120	11.7	26.7	3.8	10.0 mm
320	240	23.4	53.4	7.6	16.0 mm



# How to Access the Product Manual



## Link for Accessing the Product Manuals

Simply enter the IS Number in the Search Bar, as shown above

<https://bis.gov.in/index.php/product-certification/product-specific-information-2/product-manualsmk/>

Product Manual is separate for every product and contains SIT , grouping guidelines , quantity of sample required for testing , parameters to be declared for testing etc



# Things to look for in SIT

SIT is separate for every product and is available in the product manual

Labelling and marking to be done as specified in SIT . Many times the SIT refers to the marking clause of the Indian Standard . Non compliance in marking is considered as a failure of sample

If “R” is mentioned under the column ( test equipment requirement ) against a particular test , it means that test has to be carried out inhouse. Firm shall have necessary test equipment

If “S” is mentioned under the column ( test equipment requirement ) against a particular test , it means that subcontracting is allowed for that particular test from BIS approved labs only .

List of BIS approved labs can be accessed from BIS website under laboratory services . Link given below ( copy & paste )  
[http://164.100.105.198:8096/bis\\_access/iswise\\_v2.html](http://164.100.105.198:8096/bis_access/iswise_v2.html)

Tests to be done as per the frequency mentioned in the table and records of tests to be maintained both for R and S category tests

Compliance to SIT and marking requirements is verified during surveillance visits

## 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 1): 1994.

**4. CONTROL UNIT** – All the clinical thermometers of the same pattern manufactured in a day shall constitute a control unit.

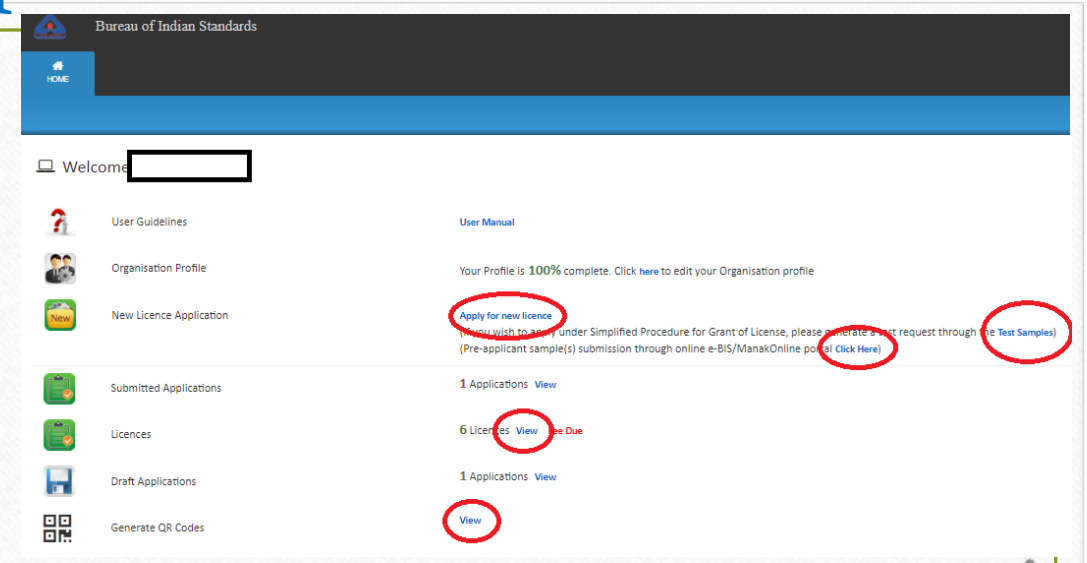
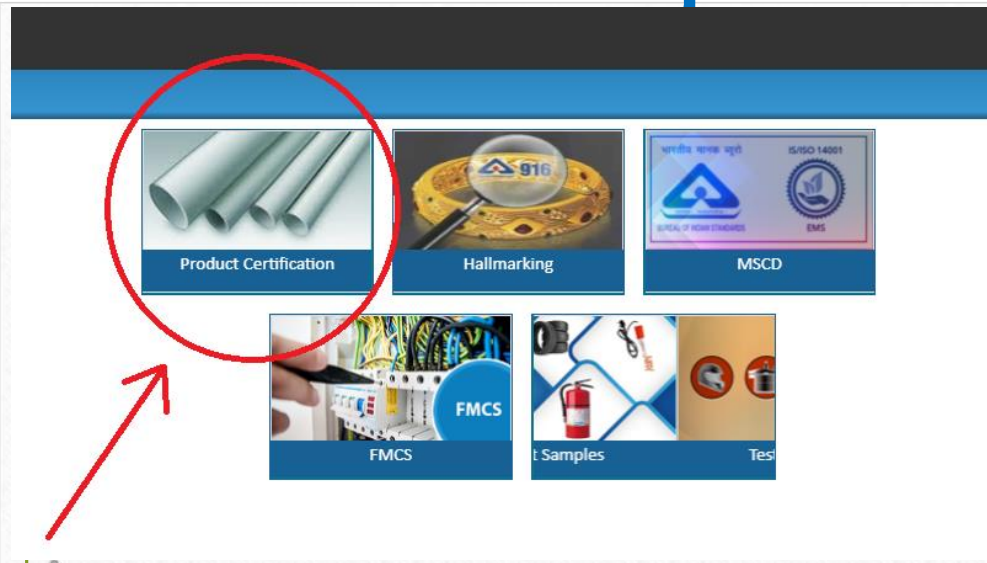
**5. LEVELS OF CONTROL** - The tests as indicated in column 1 of [Table 1](#) and the levels of control in column 3 of [Table 1](#), shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

**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

**TABLE 1**

(1) Test Details				(2) Test equipment requirement	(3) Levels of Control		
Cl.	Requirement	Test Methods		R: required (or) S: Sub-contracting permitted	No. of Sample	Frequency	Remarks
		Clause	Reference				
7.2	Materials		IS 3055 (Pt 1)		Every consignment received	#	
	Glass tubing	7.2.1		S			
	Bulb	7.2.2		S			
	Glass	7.2.3		S	One from every batch of glass used for maximum device, capillary tube & bulb received.	#	
	Thermometric liquid	7.2.4		-	-		
7.3	Construction	7.3.1 – 7.3.6	IS 3055 (Pt 1)	R	Each thermometer	Each control unit	
7.4	Dimensions	7.4 & Table 1	IS 3055 (Pt 1)	R	Each thermometer		
7.5	Graduation Numbering and	7.5.1- 7.5.7	IS 3055 (Pt 1)	R	Each thermometer		
	Permanency Marking of	7.5.8			1% with min. 5 thermometers	Each control unit	

# How to Operate and Update Manakonline



S.No.	CML No.	Firm Name	IS No.	Status	Granted Date	License Valid Till	Activity Log
1			IS 4984:2016	License Operative			<ul style="list-style-type: none"> <li>History</li> <li>Activity Log</li> <li>Communication With BIS</li> <li>Apply for Inclusion</li> <li>Make Payment</li> <li>File Your Return</li> <li>Apply For Stop Marking</li> <li>Fee Refund Details</li> <li>Discrepancy Report</li> <li>Corrective Action on Discrepancies</li> <li>Fill Top Management Details</li> <li>Fill Technical Persons Details</li> <li>Upload Manufacturing Process Flow Chart</li> <li>Upload Layout Plan of Factory</li> <li>Upload Manufacturing Machinery List</li> <li>Upload Testing Equipment List</li> <li>Upload Form of Label</li> <li>Upload Hygienic Condition Document</li> <li>Raw Material Details</li> <li>Add Consignee Details</li> <li>Update Weekly Off</li> <li>View Test Request</li> </ul>

## THINGS TO DO IN MANAKONLINE

1. Check communication window on daily basis
2. Update all consignee details mandatorily on quarterly basis
3. Samples for inclusion purpose to be sent to labs through LIMS mandatorily, Apply for inclusion after receipt of test report from Lab through LIMS
4. Samples for simplified applications to be sent to labs through LIMS only . Apply for new licence after receipt of test report from lab through LIMS
5. Update and upload necessary details as sought by inspecting officer of BIS / BIS approved outside agency during the inspection itself
6. Update weekly off
7. Check for renewal alerts
8. Apply renewal at least 2 months before expiry of validity of licence



# Assistance / cooperation during inspection

Provide all assistance and cooperation to the inspecting officer during the visit for the purpose of inspection

Provide the samples as required for the purpose of inspection and sampling

Provide records of testing , calibration, raw materials, consignee for the purpose of inspection and sampling

Upload all necessary details in Manakonline which are sought by inspecting officer for the purpose of inspection

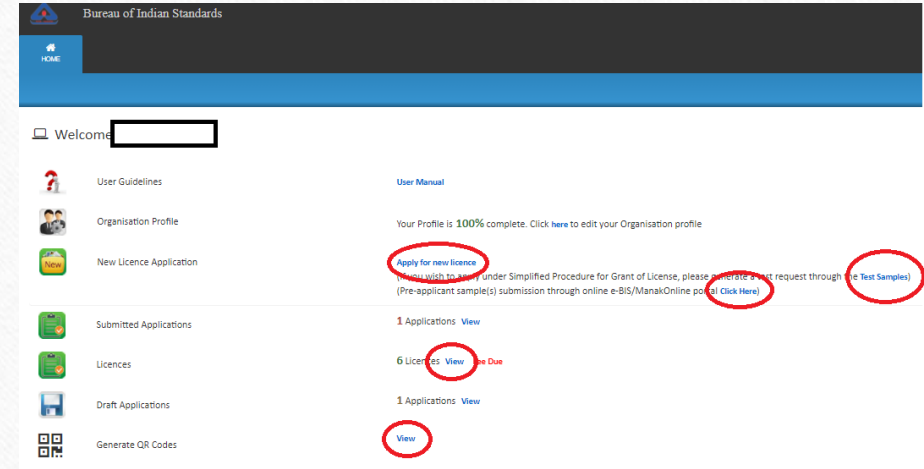
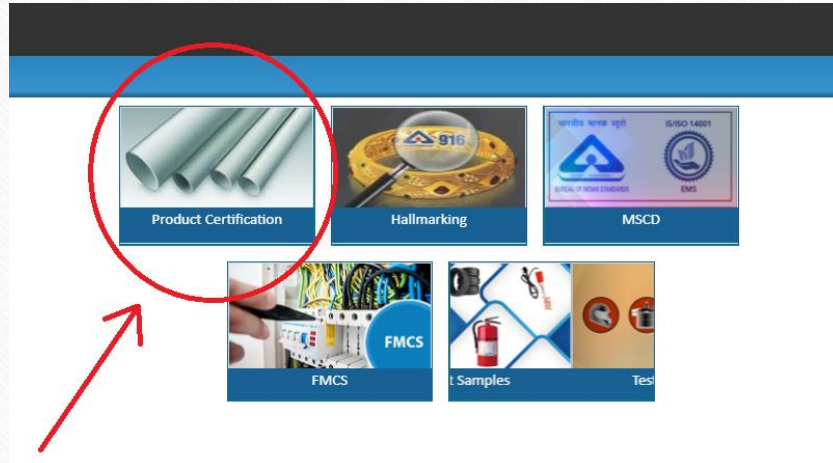
CML No. ↕	Firm Name ↕	IS No. ↕	Status ↕	Granted Date	License Valid Till	Activity Log
		IS 4984:2016	License Operative			<ul style="list-style-type: none"><li>History</li><li>Activity Log</li><li>Communication With BIS</li><li>Apply for Inclusion</li><li>Make Payment</li><li>File Your Return</li><li>Apply For Stop Marking</li><li>Fee Refund Details</li><li>Discrepancy Report</li><li>Corrective Action on Discrepancies</li><li>Fill Top Management Details</li><li>Fill Technical Persons Details</li><li>Upload Manufacturing Process Flow Chart</li><li>Upload Layout Plan of Factory</li><li>Upload Manufacturing Machinery List</li><li>Upload Testing Equipment List</li><li>Upload Form of Label</li><li>Upload Hygienic Condition Document</li><li>Raw Material Details</li><li>Add Consignee Details</li><li>Update Weekly Off</li><li>View Test Request</li></ul>

**USING MANAKONLINE DURING SURVEILLANCE**

1. Update top management details
2. Update technical person details
3. Manufacturing process flowchart
4. Layout plan of factory
5. Manufacturing machinery list
6. Test equipment list
7. Labels used
8. Hygeinic conditions document ( if applicable )
9. Raw material list and evidence of conformity to requirements of standard
10. Consignee details



# Inclusion sample - How to Generate QR Code



**QR Code Generation**

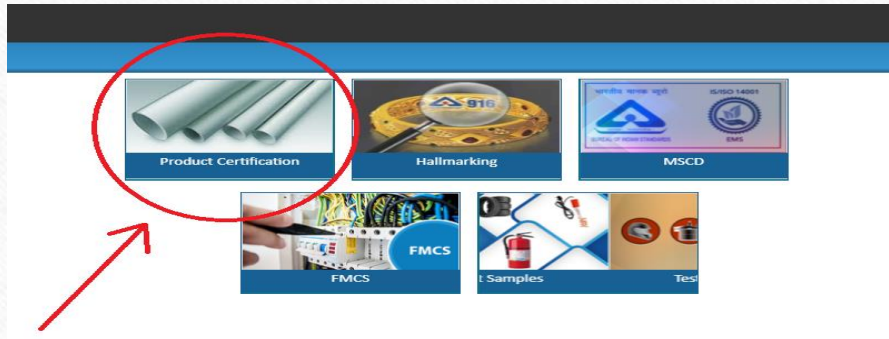
Not Used Codes

**Available Codes**

Show  entries

	S. No.	Qr Code	Generaton Date	Generated By	Used Status	Sample Code	Scan Date
<input type="checkbox"/>	1	100000033199	2021-05-13 11:52:28.0		Not Scanned	N/A	N/A
<input type="checkbox"/>	2	100000033200	2021-05-13 11:52:28.0		Not Scanned	N/A	N/A
<input type="checkbox"/>	3	100000033201	2021-05-13 11:52:28.0		Not Scanned	N/A	N/A
<input type="checkbox"/>	4	100000033202	2021-05-13 11:52:28.0		Not Scanned	N/A	N/A
<input type="checkbox"/>	5	100000033203	2021-05-13 11:52:28.0		Not Scanned	N/A	N/A
<input type="checkbox"/>	6	100000033204	2021-05-13 11:52:28.0		Not Scanned	N/A	N/A
<input type="checkbox"/>	7	100000033205	2021-05-13 11:52:28.0		Not Scanned	N/A	N/A

# How to Generate Test Request in LIMS



Mention complete details of the sample in test request .  
For assistance pl check product manual

Send sufficient quantity of sample for testing – Pl refer  
product manual for assistance

Send samples to BIS approved labs only – Pl check  
status of labs from BIS website on the day of generating  
test request Link given below.

[http://164.100.105.198:8096/bis\\_access/iswise\\_v2.html](http://164.100.105.198:8096/bis_access/iswise_v2.html)

Apply for inclusion immediately on receipt of test report  
through LIMS and not later than 90 days

