

Instructions to applicants while submitting applications for Scheme-X (OTR) under FMCS

1. A dedicated module of Manak Online catering to products notified for compliance under Scheme-X (OTR) of the BIS Conformity Assessment regulations is under development at present for Foreign Manufacturers. As the roll out of this module is expected to take some time, Applications for GoL can be submitted through hard copies (by courier/post or in person) for products notified for compulsory BIS license under Scheme-X (OTR).

Applications may be sent at the following address:

Head (Foreign Manufacturers Certification Department)
Room No. G-17/18, Manakalaya,
9 Bahadur Shah Zafar Marg, New Delhi - 110002 INDIA

2. (a) The General Guidelines for Grant of licence and schedule of payment applicable for the applicants and licensees under Scheme-X have been issued by BIS and can be accessed at the link mentioned below.

<https://www.bis.gov.in/wp-content/uploads/2025/07/OTR-Guidelines-Grant-of-Certification-SafetyOfMachinery.pdf>

(b) The product specific guidelines for Omnibus Technical Regulations on Machine Safety can be accessed at <https://www.bis.gov.in/scheme-x-certification/product-specific-information/?lang=en>

Applicants are advised to go through the above guidelines before the submission of the application to ensure the completeness of the application.

3. Applicants may submit new application(s) for grant of licence along with technical file for each series of the machine that the applicant desires to include in the scope of the licence.

4. Selection of IS: The applicants will be required to choose the Indian Standard (IS) for which the application is being submitted. Applications for machine or electrical equipment specified in the First Schedule of Machinery and Electrical Equipment Safety (Omnibus Technical Regulation) Order, 2024 shall be filed as per corresponding Indian Standards, as applicable, as given below: -

(a) Type A standards i.e. IS 16819:2018/ISO 12100:2010 (Safety of Machinery General Principles for Design-Risk Assessment and Risk Reduction

(b) Type B Standards –as per the second schedule

(c) Type C Standards – as per the third Schedule

Provided that if a Type C standard deviates from one or more technical provisions dealt with by Type A or Type B standard, Type C standards shall take precedence.

5. The applicant may clearly indicate the varieties applied for in the Application Form or in a separate Annexure. The documents to be submitted in Application and Technical File are indicated at Annexure – I.

6. The applicant has to ensure that all the relevant fields in the application form are appropriately mentioned such as Details of Contact Person and Authorized Indian Representative, Management Details, Raw material details and production details, Process flow chart, plant layout and list of manufacturing machinery and testing equipment. These documents are to be submitted along with the application and Technical File along with necessary undertakings.

The details of Fee applicable for the application is given in Annex-V of General Guidelines for Grant of licence. For applicants under FMCS additional fees is applicable such as Travel and Visa charges, Per-diem charges for the nominated auditor(s) for the duration of the audit and contingency charges which will be intimated to the applicant once the Audit team is allotted.

7. Nomination of Authorized Indian Representative (AIR) by foreign manufacturers is mandatory. Please refer Annex-IV of General Guidelines for Grant of licence.

Annexure- I

1. The application shall consist of the following documents:
 - i) Name and Address Proof of the Factory (Any document issued by Government Authority indicating the address of the factory)
 - ii) Authorized representative letter in case the application is signed by person other than CEO of the firm.
 - iii) Manufacturing Process flow chart
 - iv) Manufacturing Machinery List
 - v) Details of manufacturing operations outsourced, if any
 - vi) Agreement of outsourcing of manufacturing operation, if applicable
 - vii) List of Testing Equipment
 - viii) Details of Testing Arrangements outside the factory, if any
 - ix) Valid Calibration Certificates of the Testing Equipment
 - x) Technical File
2. The technical file shall consist of the following documents:
 - i) Product description with details of variety or grades or type or size as applicable
 - ii) Specified requirements applicable for the product
 - iii) Photograph (s) for identification of the product
 - iv) Manufacturer's name and complete address
 - v) Detail for identification and traceability of product like brand name, trade mark, date of manufacturing, batch or lot or serial number etc. as applicable. In case of application for certificate of conformity, quantity along with batch/lot/serial number details shall also be submitted.
 - vi) Detail of design of the product including drawing(s) as applicable - only to extent applicable required to demonstrate safety compliance as per specified requirements
 - vii) Description of manufacturing process as relevant
 - viii) Product Compliance Report to all applicable specified requirements by the manufacturer's own (including sub-contracted arrangements) laboratory covering aspects such as
 - a) Risk assessment including hazards identification and related risk reduction measures
 - b) Safety function diagrams like stroke limitation, electrical circuit, ground connection, hydraulic circuit, pneumatic circuit
 - c) Safety validation reports with performance level of safety related parts / control systems (SRP/CS)
 - d) Wherever in product compliance report reference is made to requirements of components (like safeguarding devices), following documents may be provided for the details:
 - A) BIS certificate of components
 - B) Original manufacturer's test certificate or data sheet
 - C) Test Report from any BIS recognised / empanelled laboratory
 - D) Test Report from the applicant manufacturer's own (including sub-contracted arrangements) laboratory
 - E) Test report from accredited laboratory
 - ix) Details of in-house quality assurance measures including inspection, test plan and facilities, as applicable
 - x) Instructions for use, maintenance, installation, safe operation of the product; as applicable
 - xi) Any other requirement specified for the product.

CHECK-LIST FOR APPLICATION TO BE SUBMITTED BY APPLICANT TO BIS WHILE APPLYING FOR BIS LICENCE UNDER SCHEME-X OF BIS

The following check-list is required to be submitted with all the applications for grant of BIS licence under Scheme-X of BIS.

No.	Check-point	Requirement	Observations	Page No.
	General	Is the application form completely filled?		
1.	Name & Address	Is the name and address of applicant (manufacturing unit applying for licence) same in the application as given in the attached document (Address Proof document)		
2.	IS No. & Varieties	a. Has applicant recorded the applicable Indian Standard with correct title of the Standard?		
		b. Where applicable, has applicant mentioned designation, grade, type, variety, size, etc., of the product for which the BIS licence is sought?		
3.	History	a. Where applicable, has the applicant provided information regarding earlier BIS licence(s) held by them and / or cancelled in the past?		
		b. Where applicable, has the applicant provided information regarding BIS licences currently held by them?		
4.	Signature	a. Is the application signed by the CEO of the applicant?		
		b. In case the application is signed by a person other than the CEO, is the application signed by the authorized signatory of the applicant and his authorization is attached by the authorized signatory?		
5.	Machinery	a. Does applicant possess requisite manufacturing infrastructure to manufacture the product as per the Indian Standard?		
		b. Is installed capacity of production indicated in the application?		
		c. Does applicant have all machineries installed as per manufacturing process at the applicant manufacturing premises?		
		d. If answer to 'c' above is no, does the applicant outsource any of its manufacturing processes and possesses valid agreement(s) with other manufacturing units for the outsourced processes and traceability of material, thus produced, etc.?		
		e. If answer to 'd' above is yes, does the applicant has any control over such outsourced activity? Are this outsourced process will ensure testing the quality of final product for all requirements at the applicant's manufacturing premises?		
6.	Test Equipment & Calibration	a. Does applicant possesses requisite test facilities in-house as per the relevant Indian Standard at its factory address?		
		b. Are valid calibration certificates for relevant test equipment attached are complete and valid at least 3 months after the date of recording?		

7.	QC personnel	Does the applicant employ qualified & experienced Quality Control (QC) personnel on permanent basis and possess documentary evidence to establish the same? Are the copies of the qualification certificates and appointment letters of the QC personnel are in order.		
8.	Raw Materials and Components	Where ever requirements for raw materials/ components used in the manufacturing of the product are specified in the standard, do test reports/suppliers' test certificates, as submitted by the applicant show that these requirements are met as per the standard?		
9.	Plant Layout	Does copy of the plant (applicant manufacturing premises) layout clearly indicates locations of manufacturing machinery, laboratory, office, workshop, amenities, storage area, etc.?		
10.	Test Report(s)	a. Is the attached test report of in-house or from independent laboratory cover all requirements of the Indian Standard and is passing in such requirements. (as per the relevant Standard mentioned in OTR)- Type Standard to be mentioned in the Application and Technical File.		
11	Technical File	Whether separate Technical File is submitted for each series by the applicant?		
12	Risk Assessment Report	Whether Risk Assessment Report has been attached with the Technical File and all the parameters have been reported as per IS 16189:2018/ISO 12100:2010.		

**SPECIFIC REQUIREMENTS FOR APPLICANTS UNDER
FOREIGN MANUFACTURERS' CERTIFICATION SCHEME OF BIS**

Sl. No.	Check-point	Requirement	Yes	Not Applicable
15.	Application Fee	Has applicant paid requisite application fee of Rs. 1000/-, in equivalent US\$ (Rs. 1000/- plus taxes, as applicable for applicants from SAARC countries only)?		
16.	Signature	Is the application countersigned by the applicant's Authorized Indian Representative?		
17.	Nomination	a. Has 'Nomination Form' of 'authorized Indian representative (AIR)' in the prescribed format on the firm's letter-head, duly signed by the authorized signatory of the applicant and the AIR or the authorized person of the company of the AIR, been submitted with the application?		
		b. Whether the person nominated as AIR is a graduate? Is the copy of the qualification certificate attached?		
		c. Is the authorization to the signing authority to sign the 'Nomination Form' on behalf of the Indian Co. also submitted?		
		d. Is address of the AIR in the 'Nomination Form' complete and evidence of nationality, address proof, contact details like phone / fax numbers and e-mail address of the AIR submitted?		
		e. In case AIR is an Indian company, have copies of registration certificate and/or Memorandum of Articles along with authorization letter from top management of the Indian company in the name of a person acting as the AIR also been submitted with the application?		
		f. Has copy of Agreement between applicant and the Indian company / individual, nominated as the AIR, also been submitted?		
		g. Are copies of valid RBI clearance certificate for Indian Office / Branch of the applicant or any other relevant document for establishment of its Office / Branch in India provided?		
18.	Language	Are English translations of all the documents, which are in languages other than English, also available?		
19.	Preliminary Inspection / Visit Charges	Does the applicant undertake to bear inspection charges for all the inspections to be carried out by BIS at its premises before the grant of licence, including the arrangements and costs incidental thereto for travel and stay, visa, insurance, etc.?		
20.	Translation Facility	Does the applicant undertake to arrange, if required, services of translator (for translation in English) during the visits of BIS officers to its factory?		
21.	Agreement	Does the applicant agree to sign a legally binding agreement with BIS in the prescribed format?		
22.	Indemnity Bond	Does the applicant agree to submit an Indemnity Bond to BIS in the prescribed format?		
23.	Performance Bank Guarantee	Does the applicant agree to furnish a Performance Bank Guarantee to BIS of US \$ 10000/- (from a bank having its branch in India) in the prescribed format on the letter-head of the bank?		

Checklist for Technical File

1. Name of the applicant-
2. Address –
3. IS No. –

Technical File Checklist

Sl. No.	Requirements	Remarks (if any)														
1.	Details of Product (i.e Model or variety or grades or type)															
2.	Photograph(s) of the product															
3.	Detail of design and drawing of the product															
4.	Details of Raw material and Components															
5.	Plant Location															
6.	Plant Layout															
7.	Manufacturing Machinery															
8.	Any sub-contracting agreement (Y/N) for manufacturing. If yes, copy of agreement or consent letter for the sub - contracting arrangements (if any)															
9.	Process flow chart															
10.	In- process control															
11.	Quality assurance personnel details															
12.	Test equipment list															
13.	If any sub-contracting arrangements done, consent letter about the contractual arrangement															
14.	Marking on product															
15.	Risk Assessment Report (Mention details of risk assessment as per IS 16189:2018/ISO 12100:2010)															
	<table><tr><td>Sl. No</td><td>Report No.</td><td>Date of Issue</td><td>IS No.</td><td>Model No.</td><td>Variety Tested</td><td>Pass /Fail</td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>		Sl. No	Report No.	Date of Issue	IS No.	Model No.	Variety Tested	Pass /Fail							
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16.	Instruction manual / product manual															