

India is raising the bar on industrial safety and compliance with the rollout of the Omnibus Technical Regulation (OTR) for Machinery and Electrical Equipment Safety—a landmark regulation issued by the Ministry of Heavy Industries and enforced by the Bureau of Indian Standards (BIS). Effective August 28, 2025, this regulation mandates BIS certification for 20 categories of critical machinery and electrical equipment, including their assemblies, sub-assemblies, and components, before they can be sold or distributed in the Indian market.

The OTR introduces mandatory certification under Scheme X of the BIS (Conformity Assessment)
Regulations, 2018, which was refined in 2022 to address high-risk industrial products. Its goal: bring Indian safety norms in line with international standards while protecting users from substandard or unsafe machinery.

For foreign manufacturers, the implications are direct and non-negotiable—BIS certification must be obtained under the Foreign Manufacturers Certification Scheme (FMCS). Without it, products will be denied entry into India's vast and fast-growing industrial market. Additionally, importers, distributors, and suppliers in India must ensure their overseas partners are fully compliant, or risk supply chain disruptions and enforcement actions.

As the enforcement deadline approaches, BIS has begun cracking down on non-compliance, including raids on e-commerce platforms selling uncertified goods—signalling a firm stance on product safety and regulatory adherence.

With its vast opportunities, India is an attractive destination for global manufacturers—but only those who align with BIS requirements will be allowed to compete. The following guide explores the FMCS framework, its application process, compliance obligations, and strategic benefits, helping foreign manufacturers navigate the certification landscape well before the 2025 deadline.

#### **Overview of FMCS**

FMCS is a key initiative under BIS, enabling foreign manufacturers to certify their products as per Indian Standards. This certification is either mandatory (for regulated products) or voluntary (for non-regulated products). However, Electronics & IT Goods under the Compulsory Registration Scheme (CRS) are excluded from FMCS. Licenses under FMCS are issued by BIS headquarters in New Delhi.

## **Key Requirements for FMCS**

To qualify for FMCS certification, foreign manufacturers must meet the following criteria:

- Product Compliance: Products must conform to relevant Indian Standards (IS).
- Manufacturing & Testing Facilities: Adequate inhouse manufacturing and testing capabilities must be available.
- Authorized Indian Representative (AIR):
   Manufacturers must appoint an AIR to liaise with BIS.
- Acceptance of BIS Terms: Manufacturers must comply with all BIS regulations, testing protocols, and licensing conditions.

#### **FMCS Certification Process**

The process of obtaining a BIS license under FMCS involves multiple steps to ensure strict adherence to Indian Standards.

#### 1. Application Submission

Foreign manufacturers must submit a complete application with all required documents to BIS headquarters in New Delhi.

#### 2. Document Scrutiny

BIS evaluates the application for compliance with Indian Standards. This includes verifying the manufacturing process, quality control systems and testing facilities.

## 3. Factory Inspection

BIS officials conduct on-site inspections to assess manufacturing capabilities and ensure adherence to Indian Standards.

## 4. Independent Testing

Product samples are collected and sent to BIS-recognized laboratories for independent testing. The test results determine compliance with prescribed standards.

#### 5. Fee Payment

Applicants must pay the necessary fees, including those for:

- · Application processing
- · Factory audit
- Testing and licensing

## **License Validity & Surveillance**

Once granted, a BIS license under FMCS is initially valid for 1-2 years and can be renewed for up to five years.

BIS enforces stringent surveillance mechanisms to ensure continued compliance including:

- Factory Inspections: BIS conducts periodic visits to manufacturing units to verify compliance.
- Market Inspections: Random product samples are collected from the market for testing.
- Data Collection & Sample Testing: BIS regularly collects production data and independently tests samples.

## **Additional Provisions in FMCS**

Inclusion of New Product Varieties: Manufacturers
can add new product categories to an existing license,
provided test reports confirm compliance.

- License Renewal: To renew an FMCS license, the manufacturer must ensure continued compliance with BIS regulations and testing standards.
- Testing at BIS-Recognized Laboratories: All required tests must be conducted at BIS-approved laboratories to maintain certification.

# Benefits of Obtaining a FMCS Certification for Foreign Manufacturers

- Market Access: FMCS certification is often mandatory for regulated products, making it essential for entry into the Indian market.
- 2. **Quality Assurance:** The BIS Standard Mark assures consumers of high product quality and safety.
- 3. **Regulatory Compliance:** Ensures manufacturers meet Indian regulatory requirements, avoiding legal hurdles.
- 4. **Enhanced Consumer Trust:** Certified products gain credibility and trust among Indian consumers.
- 5. **Competitive Advantage:** FMCS-certified products enjoy a market edge over non-certified competitors.

## **Challenges Faced in FMCS Implementation**

Despite its benefits, foreign manufacturers may encounter challenges while obtaining FMCS certification, including:

- Complex Documentation: The application process requires extensive paperwork and compliance verification.
- Time-Consuming Inspections: Factory inspections and sample testing can be time consuming and resource intensive.
- Cost Implications: Fees associated with certification, inspections, and renewals can be significant.
- Regulatory Changes: Frequent updates in BIS standards may require ongoing adjustments by manufacturers.

## Conclusion

The BIS Foreign Manufacturers Certification Scheme (FMCS) is a key certification program for foreign manufacturers entering the Indian market. The process is rigorous, but it ensures product quality, regulatory compliance, and consumer trust. By following FMCS guidelines, manufacturers can seamlessly enter the Indian market, expand their customer base and build trust with consumers.

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