

# About GPC

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*“Our capacity has gone from local to global.”*



We were founded in 2008, Lund Sweden.



We offer excellent representative and compliance management services globally.



8 offices worldwide & 2 laboratories



Today, we have more than 1500 happy clients worldwide, 99% retention rate.

# Services

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We have an elaborate portfolio of 15,000+ substances.



Authoring a large portfolio of 5,000+ REACH and 500+ CLP compliant SDS and e-SDSs in 30+ languages.



750+ Lead registration & consortia management.

“

*We have followed our clients to new countries and markets which has made us expand our business and knowledge capacity worldwide.*

”



# BIS Certification Scheme: Knowing your compliance obligations



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# Summary of Topics

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- Bifurcation of Indian Standards
- How are Indian Standards linked to BIS certification
- Why do we need BIS certification?
- Who can submit application to BIS?
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# Background

## ➤ Bureau of Indian Standards (BIS)

- National Standard Body of India established for the harmonious development of the standardization activities, marking and certification of goods
- Established under BIS Act 2016

## ➤ Indian Standards

- **The standard document published by the BIS, with regards to any article or process that is indicative of the quality and specification of the article or process**
- **Acts like a guide for the manufacturers**



Through standardization, certification and testing, BIS provides benefits to the national economy by:

- Providing safe, reliable and quality goods
- Minimizing health hazards to consumers
- Protecting the environment
- Promoting exports and imports substitute
- Controlling proliferation of varieties, etc

# Bifurcation of Indian Standards

In general, Indian standards are divided into following parts:

1. Foreword
2. Scope
3. References
4. Requirements (generally mentioned in Table 1 of Indian Standard)
5. Packing and Marking criteria
6. Sampling
7. Criteria for conformity
8. Quality of reagents
9. Annex

# How are Indian Standards linked to BIS Certification? (1)

- One can apply for BIS registration against a particular Indian standard.
- To apply for BIS registration, the standards should be under compulsory or voluntary certification.
- In case of any product or chemical that has no available Indian standard or the standard is under voluntary certification, the product may be exempted from BIS registration.

**However, for the products under mandatory certification, registration is required!**

# How are Indian Standards linked to BIS Certification? (2)

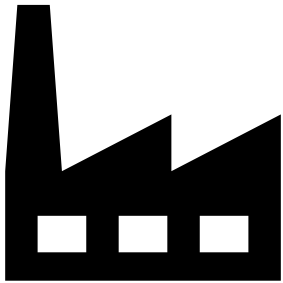
- If some organization wants to get BIS certification, If company wants to apply for BIS certification when there is no Indian standard for this specific product, company can send the request to BIS for the “Proposal of New Standard”.
- Application via BIS website.
- Once the request is taken up and the standard is formulated, the license can be granted after fulfilling the requirements.
- There is no fees for proposing a new standard.
- The timeline for formulation of the standard may vary depending on various factors.



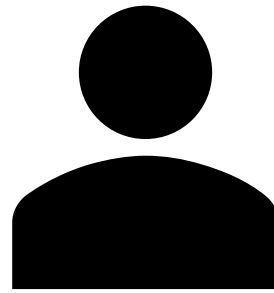
# Why do we need BIS Registration?

- BIS certification is a means for providing third party guarantee of quality, safety, and reliability of products to the customers.
- Products under compulsory certification cannot be manufactured or imported to India without the standard mark.
- All the products under **compulsory certification** need to have standard mark before they are placed in the Indian market.

# Who can submit application to BIS?



**Indian Manufacturers**



**Authorized Indian  
Representative (AIR)**  
appointed by foreign manufacturers

# Applying for BIS Registration Process (1)

<b>Application Submission</b>	<ul style="list-style-type: none"><li>• For Indian Manufacturers, application can be submitted through "BIS online portal".</li><li>• For Foreign manufacturers, offline mode of application is available. No online portal is available for them. Application form is filled along with prescribed documentation. Nomination form is filled for AIR. The same is submitted along with required fees to FMCD, BIS Headquarters, New Delhi.</li><li>• The list of documents required is almost the same for Indian and Foreign manufacturers.</li></ul>
<b>Required Documents for Submission</b>	<ul style="list-style-type: none"><li>• Checklist has been given by BIS for the submission of documents.</li><li>• Required technical documents are product manual, certificate of analysis for products &amp; raw material, equipment details, test report/requirements corresponding to Indian standards, calibration certificates for Instruments, manufacturing machinery details, and process flow chart.</li><li>• Required general details include organization name, address, management details, laboratory-in-charge details, phone numbers of management, and IS Number.</li></ul>

# Applying for BIS Registration Process (2)

<p><b>Review Process</b></p>	<ul style="list-style-type: none"> <li>• BIS officer in charge will review the documents. He may ask if some document is missing.</li> <li>• Officer will communicate with the manufacturer.</li> <li>• Afterwards, factory audit will be conducted by BIS official. The sample is tested from a third party lab and checked if the requirements matches with the Indian standard.</li> <li>• License is granted after successful factory audit.</li> </ul>
<p><b>BIS Fees &amp; Bank Guarantee</b></p>	<ul style="list-style-type: none"> <li>• There is an application fee and a marking fee which is required to be paid. The marking fee for BIS differs as per the size of the company i.e. large scale, medium, small scale manufacturer. It also differs for each product/standard. There is a minimum marking fee + per unit fee.</li> <li>• There is also a testing fee which is different for each standard and is directly paid by the client to BIS.</li> <li>• For foreign manufacturers, bank guarantee of 10000 USD also needs to be submitted. For Indian manufacturers, no bank guarantee is required.</li> </ul>



# Products under compulsory certification

BIS Certification Scheme I	BIS certification Scheme II
Also known as the ISI scheme, a licensing scheme.	A compulsory registration scheme.
Factory audit is mandatory.	Factory audit is not required.
There is a list of 381 products given by BIS which are covered under scheme I, which includes chemicals, steel, automobile parts, etc.	It is mostly applied to electronic and IT products like mobiles, adaptors, batteries, etc. There are only 3 chemicals listed under this scheme.
It is a quality and safety assurance certification.	It is a safety certification for products coming to Indian Markets.
Mode of application is online for Indian Manufacturers and offline for foreign manufacturers.	Application process is online for Indian as well as foreign manufacturers.



# Timeline

- Timeline to get BIS registration certificate under Scheme I is 3-4 months for Indian Manufacturer and about 6 months for foreign manufacturer. This timeline may vary if some query arises at the time of submission or at the time of testing.
- The License is initially granted for not less than 1 year and up to 2 years. After which license needs to renewed for not less than 1 year and up to 5 years.

# Applying for BIS registration:

## Points to Remember for BIS registration

- ✓ For **Foreign manufacturers** to apply for BIS registration, it is mandatory to appoint an **Authorized Indian Representative (AIR)**.
- ✓ Chemicals need to have purity level as mentioned in the applicable BIS standard and they need to be tested as per the test methods given in the standard.
- ✓ List of manufacturing machinery and test equipment needs to be submitted as a part of documentation.
- ✓ Plant Layout (copy) indicating location of manufacturing machinery, laboratory, workshop, office, storage area, etc., should be submitted in the application.
- ✓ In case documents are written in other languages other than English, English translation of such documents is required.

# Chemicals Regulated under BIS

Chemicals are regulated under Scheme I of BIS.

Around 60 chemicals under the mandatory certification list Scheme I and 3 chemicals are under mandatory list Scheme II.

Factory audit is required for BIS certification under Scheme I.

Application process under Scheme I is online.

Regulated Chemicals needs to be tested as per applicable Indian Standard.



# Chemicals regulated under BIS: Mandatory List (Scheme I)

Caustic Soda -Specification	Pyridine	Phosphorous Trichloride, pure and Analytical Reagent	Sodium Tripolyphosphate, Anhydrous, Technical
Boric Acid – Specification	Gamma Picoline	Phosphorous Pentachloride, Technical	n- Butyl Acrylate
Poly Aluminium Chloride	Beta Picoline	Phosphorous Oxychloride, Technical	Ether
Acetic Acid	Morpholine	Stabilized Hydrogen Peroxide	Ethylene Glycol
Aniline	Sodium Sulphide, Technical	Precipitated Barium Carbonate, Technical	Toluene
Methanol	Potassium Carbonate, Anhydrous	Precipitated Barium for Ceramic and Glass Industry	Terephthalic Acid
Specification for Phthalic Anhydride, Technical	Acetone	Sodium Formaldehyde Sulphoxylate	Methyl Acrylate

# Chemicals regulated under BIS: Mandatory List (Scheme I)

Ethyl Acrylate	Polyester Industrial Yarn (IDY)	Polycarbonate	Rice Bran Fatty Acids
Vinyl Acetate Monomer	Polyester Partially Oriented Yarn (POY)	Polyurethanes	Coconut Fatty Acids
Styrene (Vinyl Benzene)	Polyester Staple Fibres (PSF)	Vinyl Chloride Monomer	Rubberseed Fatty Acids
Maleic Anhydride, Technical	i) Polyethylene Material for moulding and extrusion ii) Low Density Polyethylene (LDPE) iii) Linear Low-Density Polyethylene (LLDPE) High Density Polyethylene (HDPE)	1,3 Phenylenediamine	Hydrogenated Rice Bran Fatty Acids
Acrylonitrile	Styrene-Butadiene Rubber Latex	Lauric Acid	p-xylene
100 Percent. Polyester Spun Grey and White Yarn (PSY)	Synthetic Micro-Fibres for use in Cement Based Matrix	Acid Oil	Ethylene dichloride
Polyester Continuous Filament Fully Drawn Yarn (FDY)	Linear Alkyl Benzene	Palm Fatty Acids	Acrylonitrile Butadiene Styrene
Red Phosphorus	Methylene Chloride (Dichloromethane),	3-(N, N-DiEthyl) Aminophenol	Ethylene Vinyl Acetate (EVA) Copolymers
Ethyl Acrylate	Polyester Industrial Yarn (IDY)	Polycarbonate	Rice Bran Fatty Acids

# Chemicals regulated under BIS: Mandatory List (Scheme II)

Chemical Name, Indian Standard No.
Ortho Phosphoric Acid – Specification, IS 798
Polyphosphoric Acid – Specification, IS 17439
Trimethyl Phosphite – Technical Grade, IS 17412

Audit at Factory is exempted!

# Recent updates in late 2022 and future development

- Till the end of 2022, out of 63 chemicals under mandatory list, QCO's for 25 chemicals were implemented.
- In 2023, Quality Control Orders (QCOs) for 38 chemicals will be implemented according to various deadlines.

Once the chemicals are included in the BIS mandatory list and deadline has passed, manufacturers, traders and importers will need BIS certification to be permitted to operate and they must carry the relevant BIS standards specification mark on the packaging and labels of their products.



# Recent updates in late 2022 and future development

- Proposal for new standards: 26
- Standards under wide circulation: 45
- **As per the latest update, around 58 new chemical products are under consideration that can be introduced under mandatory certification scheme of BIS.**

Check the list of 58 Chemicals: [https://www.gpcgateway.com/common/news\\_details/Nzgw/Nw/SW5kaWE](https://www.gpcgateway.com/common/news_details/Nzgw/Nw/SW5kaWE)

- **As per meeting in December 2022, 8 Chemicals were finalized for making them mandatory.**

1. Ethylene Oxide
2. Monocrotophos
3. Captafol (technical grade)
4. Anhydrous Ammonia
5. Alumina Calcined
6. Sodium Cyanide
7. Toluene Diisocyanate (TDI-80)
8. Industrial Grade Urea (Technical grade Urea)

# India extends Quality Control Order Enforcement Date for 10 substances

Substance	Initial enforcement date	New enforcement date
Morpholine	1 February 2023	1 August 2023
Acetic acid	3 February 2023	3 August 2023
Methanol	3 February 2023	3 August 2023
Aniline	3 February 2023	3 August 2023
Pyridine	13 March 2023	13 September 2023
Gamma Picoline	13 March 2023	13 September 2023
Beta Picoline	13 March 2023	13 September 2023
Potassium Carbonate	13 March 2023	13 September 2023
Acetone	13 March 2023	13 September 2023
Sodium Tripolyphosphate	13 March 2023	13 September 2023

Source: [https://www.gpcgateway.com/common/news\\_details/ODA5/Nw/SW5kaWE](https://www.gpcgateway.com/common/news_details/ODA5/Nw/SW5kaWE)

# Take Home Message

- BIS is the National Standard Body for standardization, marking and quality certification of goods.
- BIS registration is required to ensure that only quality products are available for Indian consumers.
- BIS registration is required for every product that is mentioned under the mandatory list of Scheme I and II.
- Chemicals are regulated under Scheme I.
- All documents on the checklist need to be submitted to get the certificate.
- After receiving the BIS certificate, every unit of certified product needs to have a standard mark on them before they reach the Indian market for consumers.

# Wanting to learn more about your obligations under BIS?

Book a Technical Consultation with GPC:

- One-to-one consultation on BIS requirements
- Assistance for administrative/technical documents preparation
- Supply chain communication
- BIS Registration

**Contact us at**  
**[Compliance@in.gpcregulatory.com](mailto:Compliance@in.gpcregulatory.com)**



# Thank You!

“ *Your Seamless Extension in  
Global Regulatory Compliance.* ”



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