

### Our Mission

Our mission is to empower you to inspire trust, foster excellence, and ensure safety in your organization; driving positive change for a better world.



BSI Assurance UK Ltd, BSI Group The Netherlands B.V. and BSI Group America Inc. are third party accredited/recognised certification bodies (UKAS, RvA, and MDSAP) that supply management systems assessment, certification and regulatory compliance services.

BSI and its international subsidiary companies also provide accredited third party testing, certification, inspection, and validation/verification services in support of global market access requirements. On site activities are limited to auditing, product inspection, witness testing, and reporting compliance or non-conformities, and are always conducted with a client representative present.

BSI Group The Netherlands B.V. is a fully designated EU Notified Body (Notified Body 2797), delivering rigorous independent regulatory and quality management reviews and product certifications to support CE marking and EU market access.

BSI Assurance UK Ltd also operates as UK Approved Body, providing conformity assessment services under UK regulation to support UKCA marking and compliance.







#### **Impartiality**

Our management system, testing, inspection, verification, and certification, European CE certification (2797) and UKCA certification (0086) aim to inspire confidence from the public and interested parties that an organization and/or its product certified by BSI fulfil specific requirements. In the case of CE marking and UKCA marking these meet the appropriate EU and UK Regulations, Directives respectively. This confidence depends upon many factors, including the competence of management and staff, integrity, impartiality and the perception of impartiality and the avoidance of conflicts of interest. To that end, BSI follows the principles set out in ISO/IEC standards 17021-1, 17065, 17025, 17020, 17029 as applicable and EU and UK regulatory frameworks. In addition, BSI has appointed an independent Global Impartiality Stakeholder Network (GISN) whose primary role is to safeguard BSI's impartiality. BSI is committed to act impartially in all activities it undertakes.

BSI understands its obligations for impartiality, including defining its impartiality policy and is committed to mitigating any risk to impartiality for the services it provides. This also includes a review of its impartiality risk analysis at least once a year. BSI has formal rules and/or contractual conditions to ensure that all BSI staff, regardless of the type of activity they perform, act in an impartial manner. It is recognised that the source of revenue for BSI is its client paying for certification and that this is a risk to impartiality. To obtain and maintain confidence, it is essential that BSI's decisions are based on objective evidence of conformity (or nonconformity) obtained by BSI, and that its decisions are not influenced by other interests or by other parties or by the fees paid.



#### BSI staff are not:

- The manufacturer, importer, distributor, or any other party with an economic interest in the products which they assess, nor the authorised representative of any of those parties.
- Involved in the design, manufacture, construction, marketing, installation, use, or maintenance of products for which they are designated, nor represent the parties engaged in those activities.

#### BSI staff do not:

- Engage in any activity that may conflict with their independence of judgement or integrity in relation to the work conducted by BSI.
- Offer or provide any services which may jeopardise
  the confidence in their independence, impartiality, or
  objectivity. In particular, they do not offer or provide
  consultancy services to a manufacturer, its authorised
  representative, importer, distributor, or commercial
  competitor concerning the design, manufacture,
  marketing, installation, use, or maintenance of products
  or processes under assessment, and they are not linked
  to any organization that provides consultancy services
  related to such products.

BSI staff who are former employees of, or former consultants to, a manufacturer or other economic operator are not involved in any assessment of that manufacturer or economic operator, or any companies within the same corporate group for a minimum of 2-3 years (depending on the specific scheme) following their employment or consultancy.

BSI staff are not involved in the assessment of any organization or company in which they have a financial interest, including those arising from grants or funding received from institutions or organizations with which they are affiliated.

BSI staff performance objectives and remuneration are not linked to any aspect of successful completion of conformity assessment for a manufacturer or economic operator.

BSI staff are required to declare any interests that may conflict with impartiality requirements. Any potential conflicts of interest are managed according to internal procedures that meet relevant standards and regulations. Where a conflict of interest is identified and is required to be made public, BSI will do so in an appropriate manner.



#### **Assessment planning**

The conformity assessment journey begins when the client submits an application to BSI for a product conformity assessment certificate. Once the contract is signed, BSI's conformity assessment services will commence. By signing the contract, the client confirms that no other application has been submitted to a different Notified Body/Approved Body for the same products and conformity assessment procedure.

BSI develops a certification plan covering the full certification cycle, including initial, surveillance and recertification audits, taking into account the client's size, scope, complexity of its management system, relevant performance data, and any previous audit results. Evaluation activities may include review of client technical files, assessment of product conformity, and, where applicable, product testing.

Certification maintenance involves periodic surveillance, follow-up of corrective actions, and recertification audits according to the defined cycle. The duration and structure of the certification cycle may vary depending on the applicable scheme and regulatory requirements. Fees are based on the time and resources required at each stage, with potential adjustments for additional sites or specific conditions. Fee discounts are available to small and medium-sized enterprises (SMEs), including start-ups, for MDR/IVDR Notified Body services and AI Act Notified Body services.



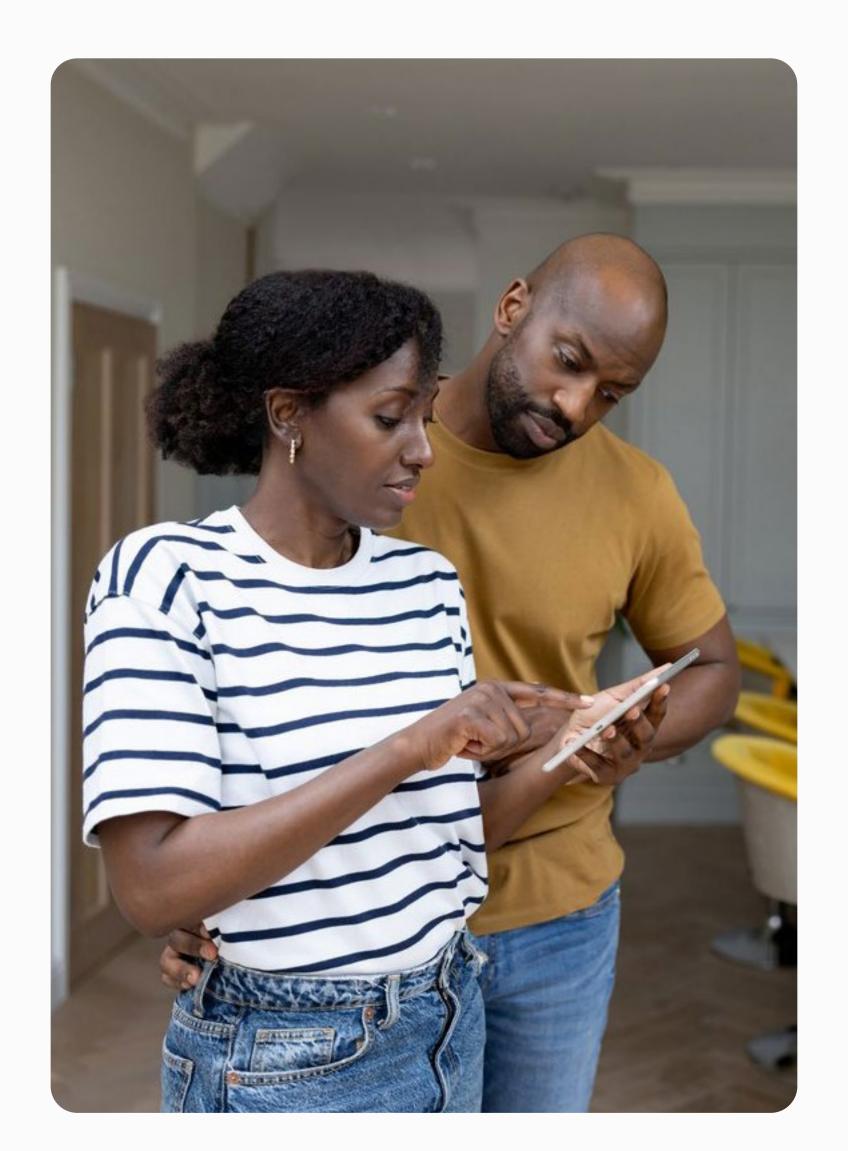
#### Certifications

Upon successful completion, BSI issues a conformity assessment certificate against product legislation and/or normative documents as required by the scheme.

BSI makes accessible information about the certification status of each of its clients through the <u>Certificate and Client Directory</u>.

#### Suspension policy

BSI may suspend or revoke a certificate if in its reasonable opinion the client does not comply with the requirements for the relevant legislation or scheme, or fails to comply with any of its obligations under the Contract, or uses BSI's services in such a manner that may be misleading or that may bring BSI into disrepute. Under suspension, the certification of a client's product or management system is invalid until the suspension is lifted.



#### Serious incident/vigilance reporting

Where applicable, a client must promptly notify the relevant Competent Authorities of any serious incident or product nonconformities that present risk to health, safety or other protected public interests. The client must also inform BSI of any such notifications made to the Competent Authorities.

Clients should refer to their specific scheme T&C or contact their BSI representative for detailed instructions. This dual notification process ensures that both regulatory and conformity assessment bodies are aware of potential risks and can take the necessary actions to protect the public and maintain compliance.



## Customer Feedback Policies and Procedures for Regulatory Services

BSI is committed to providing an efficient and responsive service to our customers and stakeholders. We welcome all feedback on performance, processes and procedures to improve and prevent further shortcomings in the future.

#### **Appeals**

An appeal is a formal request for reconsideration of any decision made by BSI concerning certification process. For instance, an appeal against a nonconformity raised by an auditor during an assessment.

Clients who disagree with a certification-related decision and are unable to resolve the issue through their Auditor/Scheme Manager or local BSI office management, may submit a formal appeal. Appeals must be submitted in writing within 21 days of receiving the decision being contested.

The notice must be addressed to the BSI RS Compliance and Risk Administrator: <a href="mailto:rscomplianceandrisk@bsigroup.com">rscomplianceandrisk@bsigroup.com</a>

Appeals will be investigated according to the BSI Regulatory Services Appeals Procedure, in compliance with the accreditation/regulatory rules governing BSI. The decision under appeal will remain in force pending the outcome of the process, which both the Client and BSI agree shall be final.

#### Complaints

A complaint is an expression of dissatisfaction, other than an appeal, by any person or organization, to BSI, relating to the activities or behaviour of someone working on behalf of BSI or the products or services of BSI.

Complaints must be addressed to the BSI RS Compliance and Risk Administrator: <a href="mailto:rscomplianceandrisk@bsigroup.com">rscomplianceandrisk@bsigroup.com</a>

We will ensure we understand your concerns fully and deal with the complaint fairly and promptly. You will be kept informed of the progress, and we will reply as soon as the complaint has been fully investigated.

For complaints regarding a certified client, please submit them in writing to the same address. Once we verify that the client is certified by BSI, we will investigate the complaint and take appropriate action if necessary. However, due to confidentiality, we cannot disclose the outcome of complaints concerning certified clients.

#### Public knowledge of complaints

BSI will not make complaints against itself or any of its client's public unless required to do so by a court of law.

#### Confidentiality

BSI understands the importance of practicing good information security and is committed to safeguarding all commercial and personal information in its charge. BSI has an established information security management system (ISMS) in line with ISO27001, the international standard for information security management, to which it is certified. Information Security Policy (PDF)

#### Data protection

BSI protects personal data in accordance with applicable data protection laws, including UK and EU GDPR. We process data lawfully and securely, and only for legitimate purposes. Personal information is retained only as long as necessary and safeguarded against unauthorised access or misuse. For data protection inquiries, please contact: <a href="mailto:privacyteam@bsigroup.com">privacyteam@bsigroup.com</a>

#### **Corporate compliance and ethics**

For more information on BSI's commitment to high standards in corporate compliance and integrity, please visit this <u>link</u>.

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# Your partner in progress

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