Your partner
in progress

Medical Devices Certification Business Policy

Our mission

Our mission is to ensure patient safety whilst supporting timely market access to medical technology in a sustainable manner. We strive to set the global standard through conducting impartial, responsive, robust and thorough conformity assessments, evaluations and certifications that are recognized and trusted worldwide.

BSI Assurance UK Ltd, BSI Group The Netherlands B.V. and BSI Group America Inc. are third party accredited / recognized certification bodies (UKAS, RvA and MDSAP) that supply management systems assessment and certification. As such, we do not perform any physical work on our client's sites apart from auditing, product inspection, witness testing and report writing. When on-site, our staff are always accompanied by a member of our client's staff.

BSI Group, The Netherlands B.V. is also a full scope Medical Devices EU Notified Body (2797) and BSI Assurance UK Ltd is also a full scope Medical Devices UK Approved Body (0086). As an EU Notified Body and a UK approved Body, BSI is dedicated to providing rigorous independent regulatory and quality management reviews and product certifications for medical devices, active implantable medical devices and in vitro diagnostic device manufacturers around the world.

Impartiality

Our management system 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 medical devices certified by BSI fulfil specified requirements. In the case of CE marking and UKCA marking these meet the appropriate EU and UK Regulations. 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 17021-1:2015**, the **EU Medical Devices Regulations** and **UK Regulations**. In addition, BSI has an appointed 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 type of activity they perform, act in an impartial manner. It is recognized 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 designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties. Such restriction does not preclude the purchase and use of assessed devices that are necessary for the operations of the notified/approved body and the conduct of the conformity assessment, or the use of such devices for personal purposes.
- Involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices 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 the manufacturer, its authorized representative, a supplier or a commercial competitor as regards the medical devices requirements for the design, construction, marketing, installation, use or maintenance/servicing of devices or processes under assessment, and are not linked to any organisation which itself provides medical devices consultancy services.

BSI staff being former employees of a medical device manufacturer or a former consultant to a medical device manufacturer are not involved in any assessment of that manufacturer or companies in the same group of companies for at least three years.

BSI staff are not involved in any assessment of organisations or companies that they have a financial interest in, including those stemming from grants and funding by organisations / institutions to which a person belongs (e.g., academia/hospitals).

BSI staff performance objectives and remuneration are not linked to any aspect of successful completion of conformity assessment for a manufacturer or the number of conformity assessments carried out.

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

The EU Notified Body & UK Approved Body top-level management impartiality declaration can be found **here**.

Certifications status

BSI makes publicly accessible information about the certification status of each of its clients through the **Certificate and Client Directory.** This shows whether a certificate is current, suspended or has been withdrawn in the last month.

Suspension policy

BSI Regulatory Services (Medical Devices) may suspend a client's certification under certain circumstances and on a case by case basis. Under suspension, the client's certification is invalid until the suspension is lifted. Such suspension will be made clear on the **BSI client directory**.

Customer Feedback Policy and Procedure 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

A request for reconsideration of any decision made by BSI related to the certification process, for example, an appeal against a nonconformity raised by an auditor during an audit. If you are a certified client of BSI Regulatory Services (Medical Devices) and have a disagreement concerning a decision related to your certification that you have been unable to resolve either through your Auditor/Scheme Manager or with the local management of your BSI office, you may make an appeal against that decision. You must contact BSI with written notice of appeal within 21 days of receipt of the outcome intended to be appealed. The notice must be addressed to BSI Regulatory Services Head of Compliance and Risk (**MedDevComplianceandRisk@bsigroup.com**).

Appeals will be investigated according to the BSI Regulatory Services appeals procedure, in compliance with the accreditation/ regulatory rules governing BSI. The decision made by BSI, which is the subject of the appeal, will remain in force pending the outcome of the appeal, which the Client and BSI each agree shall be final.

Complaints

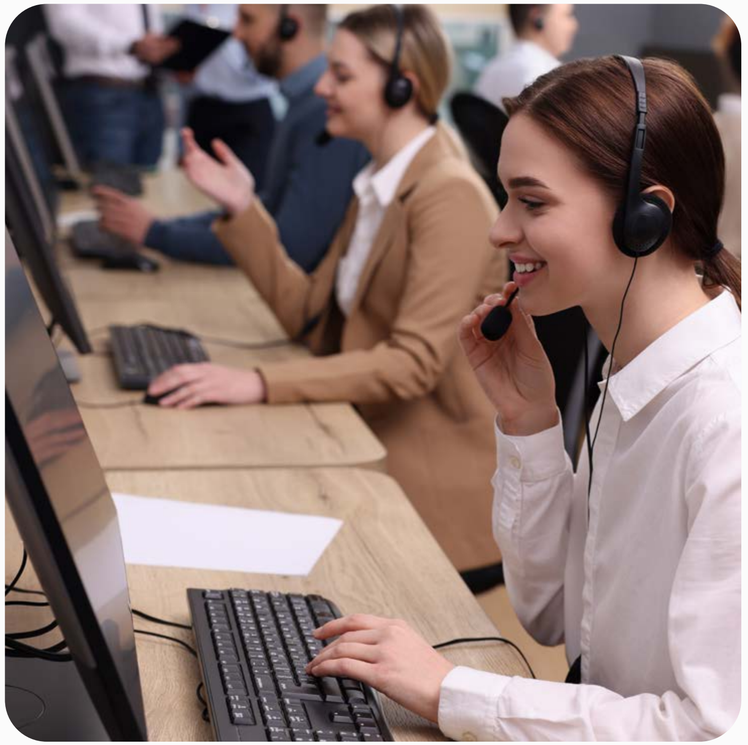
An expression of dissatisfaction, other than an appeal, by any person or organization, to BSI, relating to the activities or behaviour of someone working on behalf of BSI or the products or services of BSI.

If you are a certified client of BSI Regulatory Services and are dissatisfied with its products or services, please submit your complaint to BSI Regulatory Services Head of Compliance and Risk (**MedDevComplianceandRisk@bsigroup.com**). We will ensure we understand your concerns fully and deal with the complaint fairly and promptly. You will be kept informed of progress, and we will reply as soon as the complaint has been fully investigated.

Complaints about a certified client should also be submitted in writing, as above. Having confirmed that the subject client is certified by BSI, the complaint will be investigated, and appropriate action will be taken if and when considered necessary. However, BSI is restricted from sharing information regarding the outcome of complaints about certified clients due to reasons of confidentiality between BSI and the client in question.

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.



Contact us to discuss any feedback, email us at:
MK.customerservice@bsigroup.com
or call: **+44 345 080 9000**

Read more about our certification services on our website **bsigroup.com/medical**

Find us on **LinkedIn**