

Policy on independence, impartiality, objectivity, neutrality and confidentiality

DQS Medizinprodukte UK Ltd (DQS MED UK) is a third-party body that operates independently of the medical device manufacturer for whom we carry out conformity assessment activities. Additionally, we maintain our independence from any other stakeholders with an interest in the device, including competitors of the manufacturer. This independence does not preclude DQS MED UK from conducting conformity assessments for competing manufacturers.

We are committed to independence, objectivity, and impartiality. We have well-documented procedures and structures in place to safeguard impartiality and to uphold these principles throughout our organisation, personnel, and assessment activities. These procedures cover the identification, investigation, and resolution of any potential conflicts of interest, particularly in cases involving consultancy services related to medical devices, prior to employment of any personnel by DQS MED UK. All investigations, outcomes and resolutions are thoroughly documented.

DQS MED UK, its top-level management and personnel responsible for conformity assessments are not involved in the design, manufacture, supply, installation, purchase, use or maintenance of the devices we assess, nor do we represent any parties involved in such activities. Our focus is solely on conformity assessment activities and ensuring the independence and integrity of our judgements. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of DQS MED UK and the conduct of the conformity assessment, or the use of such devices for personal purposes.

DQS MED UK refrains from offering any services that could compromise confidence in our independence, impartiality, or objectivity, especially in relation to consultancy services for manufacturers, their authorised representatives, suppliers or commercial competitors in areas including, for example, design, construction, marketing or maintenance of devices or processes under assessment. We do not provide consultancy services and out employees have no affiliations with organisations that offer such services.

To further reinforce our independence, details of any prior involvement in consultancy services related to devices are comprehensively documented at the start of our personnel's employment with DQS MED UK, and any potential conflicts of interest are closely monitored and resolved in accordance with the applicable normative and legal requirements. Personnel formerly employed by a customer or their close competitor or who have provided consultancy services in the field of medical devices to a customer or their close competitor prior to taking up employment with DQS MED UK shall not be assigned to conformity assessment activities for that customer or companies belonging to the same group for a three-year period.

DQS MED UK guarantees the impartiality of our top-level management and assessment personnel. The remuneration of top-level management and personnel involved in assessment activities is independent of the assessment results. Declarations of interest of our top-level management are publicly available. DQS MED UK is not owned by a public entity or institution and is independent of MHRA.



DQS MED UK ensures the activities of our subcontractors, including their owners, do not compromise independence, impartiality, objectivity, neutrality, or confidentiality of our conformity assessment activities.

Our terms and conditions are consistent, fair, and reasonable, taking into account the interests of small and medium-size enterprises and multi nationals in relation to fees.

The statements set out herein in no way preclude the exchange of technical information and regulatory guidance between DQS MED UK as a certification body and a manufacturer applying for conformity assessment.

We have documented procedures in place to ensure that our personnel, committees, subcontractors, and any personnel of external bodies respect the confidentiality of information obtained during the performance of conformity assessment activities, except when disclosure is required by law.

DQS MED UK personnel maintain professional secrecy in their tasks under the conditions of accreditation and designation with exceptions regarding the authorities responsible for certification bodies and UK Approved Bodies.

We also have documented procedures in place to protect property rights.