

Declaration on independence, impartiality, objectivity, neutrality and confidentiality as well as on handling of conflicts of interest

DQS Medizinprodukte GmbH (DQS MED) is an independent third-party body that is independent of the manufacturer of the device in relation to which we perform conformity assessment activities. Furthermore, we are independent of any other economic operator having an interest in the device as well as of any competitors of the manufacturer. This does not preclude DQS MED from carrying out conformity assessment activities for competing manufacturers.

DQS MED is organised and operated in such a way as to safeguard the independence, objectivity and impartiality of our activities. We document and implement a structure and procedures for safeguarding impartiality and for promoting and applying the principles of impartiality throughout our organisation, personnel and assessment activities. Such procedures shall provide for the identification, investigation and resolution of any case in which a conflict of interest may arise, including involvement in consultancy services in the field of devices, prior to taking up employment with DQS MED. The investigation, outcome and its resolution are documented.

DQS MED, its top-level management and the personnel responsible for carrying out the conformity assessment tasks are neither designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of DQS MED and the conduct of the conformity assessment, or the use of such devices for personal purposes.

DQS MED is neither involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which we are designated, nor do we represent the parties engaged in those activities.

We are not engaged in any activity that may conflict with our independence of judgement or integrity in relation to conformity assessment activities for which we are designated.

DQS MED does not offer or provide any service which may jeopardise the confidence in our independence, impartiality or objectivity. In particular, this relates to offering or providing consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regard the design, construction, marketing or maintenance of devices or processes under assessment.

DQS MED does not offer any consultancy services. We as well as our employees are not linked to any organisation which itself provides consultancy services.

Involvement in consultancy services in the field of devices prior to taking up employment with DQS MED as an employee or auditor is comprehensively documented at the time the employment starts; and potential conflicts of interest shall be monitored and resolved in accordance with the applicable normative and legal requirements. Personnel who were formerly employed by a specific client, or provide consultancy services in the field of devices to that specific client, prior to taking up employment with DQS MED, shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group, for a period of three years.

DQS MED guarantees the impartiality of our top-level management and of the assessment personnel. The level of the remuneration of our top-level management and assessment personnel and subcontractors, involved in assessment activities, does not depend on the results of the assessments. We make the declarations of interest of our top-level management publicly available.

DQS MED is not owned by a public entity or institution.

DECLARATION OF INTEREST



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DQS MED ensures and documents that the activities of its subcontractors, including the activities of its owners, do not affect independence, impartiality, objectivity, neutrality and confidentiality of its conformity assessment activities.

DQS MED operates in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-size enterprises in relation to fees. The requirements laid down in this Section in No way preclude exchanges of technical information and regulatory guidance between DQS MED as notified body and accredited and recognised audit organisations and a manufacturer applying for conformity assessments.

DQS MED ensures by having documented procedures in place, that our personnel, committees, subcontractors, and any personnel of external bodies, respect the confidentiality of the information which comes into their possession during the performance of conformity assessment activities, except when disclosure is required by law.

DQS MED personnel observes professional secrecy in carrying out their tasks under the accreditation, notification and recognition, except vis-à-vis the authorities responsible for Notified Bodies, the authorities responsible for medical devices in the EU member states or the EU Commission, as well as the responsible accreditation bodies and regulatory authorities. Property rights are protected. DQS MED has documented procedures in this regard.

Frankfurt/Main, 16 April 2019

A handwritten signature in blue ink, appearing to read "S. Uhlemann", followed by a horizontal flourish.

Sigrid Uhlemann
Managing Director DQS Medizinprodukte GmbH