President's statement on certification quality policy

GMED is a key actor with multiple recognitions in the health industry.

GMED put the best experts at its customers' service to accompany them in their certification project in view of putting the medical devices on the market in France and internationally.

The success and the high level of performance of GMED is based on excellence, the know-how and the implication of its teams trained at the highest level on the currently applicable evaluation and certification methods.

GMED conducts missions as a certification body for quality management systems in the sense of the standard ISO 17021-1 and as a notified body in the sense of European regulation. GMED provides certification within a voluntary or regulatory framework facilitating market access to various medical devices.

GMED COMMITMENTS

GMED as management system certification body and notified body commits to meet customer's expectations and applicable regulatory and normative requirements.

In particular, GMED commits to:

- define and implement non-discriminatory management rules,
- act with impartiality towards customers,
- set necessary means to ensure the respect of confidentiality rules applicable to the staff involved,
- set measures to avoid conflicts of interest and ensure their effectiveness,
- provide necessary training to meet skills criteria for staff involved in certification. Likewise, GMED commits to provide training to the staff involved in evaluation processes and also make sure that laboratories performing compliance tests comply with ISO 17025 standard,
- ensure or contribute to the promotion and development of the different certification systems,
- ensure or contribute to the defense of corresponding collective certification marks,
- define and implement procedures to respond to complaints, appeals and disputes by taking the fairest decisions according to the concerned case.

GMED commits towards competent authorities and other certification bodies to comply with the requirements defined by regulatory texts such as European directives and regulations, and satisfy the criteria defined for its designation or recognition. Furthermore, GMED commits to respect the ethical principles defined among notified bodies. As such, GMED signed the "Code of Conduct for Notified Bodies" within the framework of medical devices directives 90/385/EEC and 93/42/EC.

To carry out its missions and fulfill these commitments, GMED has an internal organization allowing us to pilot the certification activities transparently and independently from other activities.
GMED is fully responsible for decisions related to the granting, maintenance, extension, suspension, or withdrawal of certification.

This organization gives confidence in the quality of certification services provided and helps reach quality objectives.

Its quality objectives are identified as follows:

- meet regulatory and normative requirements in terms of product certification, service, and system certification,
- meet clients' expectations by fulfilling our obligations and developing our ability to answer market needs,
- contribute to GMED efficiency.

In view to achieve these objectives, GMED commits to maintain continuous improvements to enhance the quality of its certification process. Efforts are focused on the training and information of staff and of GMED's service providers, to the monitoring of customer satisfaction and to the internal timeliness related to customer commitment.

These objectives and provisions implemented to reach them are reviewed during annual management reviews and managers' meetings using quality indicators and internal audits.

Our quality manual and the associated documents describe in detail the applied principles, our organization, and our methods to obtain and maintain the quality of our services.

Some GMED employees and its subsidiary, GMED NA, have specific responsibilities for the success of our quality policy as a certification body:

- the members of the executive committee,
- the quality manager,
- the quality engineer
- the quality assistants,
- the GMED NA subsidiary CEO and the quality correspondent at GMED NA,
- the resources qualification manager,
- the department managers.

Moreover, a Committee for Certification and Preservation of Impartiality (Comité de Certification et de Préservation de l'Impartialité) oversees specific missions related to preserving the impartiality. Among these missions are the monitoring of compliance with impartiality rules and proposition of evolutions or developments related to the matter.

With them and with the staff of GMED and GMED NA contributing to certification activities, I commit to provide all necessary means and to ensure that the certification quality manual requirements are applied.

Lionel DREUX, President
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