

The Management of Mediberg, aware that in order to obtain and maintain good results in business management it is essential to aim for continuous improvement, intends to develop its own Quality and Environmental Management System and to qualify its products to increase the competitiveness needed to face new international markets in respect of the environment, and in compliance with the relevant Community Directives.

Mediberg aims to satisfy and, if possible anticipate, the needs and expectations of its Customers, providing technically valid, performance-safe and economically competitive products and services.

Management is also focused on respecting the Mandatory Regulations and maintaining the effectiveness of the processes of the Quality Management System and the environment.

To this end, Senior Management carries out, alongside senior management figures, a risk analysis, extended to all company processes, to determine the risk/benefit relationship for each of them and to ensure their efficiency.

Mediberg's concept of Quality doesn't just concern the product; it also includes all company activities with an influence on Customer satisfaction and the safety of Devices on the market.

Quality management is a continuous and repetitive process aimed at guaranteeing a constant level of quality and safety

PRINCIPLES FOR QUALITY AND ENVIRONMENTAL MANAGEMENT

of the products and services offered by Mediberg, in accordance with the expectations of international customers, and in compliance with the relevant Community Directives. Compliance with the essential requirements of Directive 93/42 and subsequent amendments is mandatory, as is compliance with the requirements of Regulation 2017/745/EEC, which will come into effect in May 2020.

Quality management and respect for our environment are part of Mediberg's culture and strategy, affecting all company activities.

The Mediberg brand must be defended and improved by maximising the quality and safety of the product and that of all business processes, in particular the study, design, purchase, programming, production, control and sale, as well as an after-sales service that guarantees prompt and effective customer assistance.

The objective of quality management is also to guarantee valid economic compliance with quality requirements, with a view to continuously reducing costs while maintaining the high levels of quality and flexibility expected from the healthcare market, the main sector in which the company operates, by constantly monitoring the effectiveness of all quality management system processes.

Quality and environmental management must start from senior management. All managers are required to set an unequivocal example; the various business departments must consider these three aspects as fundamental and indispensable values for the success of Mediberg on the international stage.

Proper quality management means that each employee is responsible for the quality of their work.

Suppliers and subcontractors are our partners. It follows that we must work together to achieve objectives that satisfy both and ensure mutual growth both in terms of the environment and of product and service quality.

Working relationships, both internally and externally, are based on respect, honesty and integrity in the work of a team whose goal is to try to solve problems constructively.

Quality and environmental management guarantees a level of environmental protection in compliance with current national and community regulations and laws, with special attention paid to the prevention of pollution and the reduction of our environmental impact.

PROMOTION OF QUALITY AND TRAINING

Awareness of Quality and respect for the Environment constitutes the basic attitude of every employee and must always be prevalent and continuously developed through systematic promotion.

Employees are recognised by Mediberg as a strategic competitive factor. The success of the company can be achieved and maintained only through the involvement of employees at all levels, who are expected to contribute to improving company results and draw benefits from them.

In order to guarantee and strengthen the expected standards of preparation and professionalism at all levels, internal and external training courses are continually organised in relation to Quality and the Environment, health and safety issues, and professional development.

Above all, the principles of Quality and respect for the Environment in which we live must manifest themselves in our daily activity.

OBJECTIVES FOR IMPROVEMENT

The objectives for the improvement of Quality and Environmental Performance are established for the whole organisation.

They are integrated with the overall company objectives and set on increasing customer satisfaction, the effectiveness and efficiency of processes, environmental performance and safety standards and are established in such a way as to be measurable.

The strategies for achieving these goals are understood and agreed upon by all who work together to achieve them.

The improvement objectives are regularly reviewed and reflect changes in our customers' expectations.

Opportunities to reduce non-quality losses often drive improvement efforts.

Mediberg must act according to the principle that the quality of products and services arises in the design phase and in its processes, and that prevention therefore takes precedence over identifying defects and inconveniences; it must also act according to the principle that everyone is responsible for the quality of their products and services provided and their work.

The loss of customer favour and the failure to fully utilise human potential are also deemed as non-quality losses, which are difficult to measure.

Environmental performance improvement objectives are set with regard to energy consumption and waste management.

COMPANY QUALITY AND ENVIRONMENTAL MANAGEMENT

As a tool for Quality and Environmental management, the Environmental Management System Manager (RGSA) covers all company activities, ensuring compliance of Mediberg's products and services with customer expectations, and maintaining the effectiveness of the management system.

The Quality and Environmental Management System Manager has the full support of the Management and is responsible for the correct application of the Quality/Environmental System.

The System concerns all the structures, responsibilities, processes, procedures and means that Mediberg makes available in adequate quantities and qualities to ensure the expected levels and compliance with legislative requirements.

Its purpose is to create and guarantee, both internally and externally, the reasonable certainty that Quality and the expected environmental performance are constantly achieved.

The Mediberg Quality/Environmental System is described in the Management System Handbooks and is based on international standards:

UNI EN ISO 9001:2015

UNI EN ISO 14001:2015

UNI EN ISO 13485:2016

Directive 93/42/EC and subsequent amendments

Calcinato, 1 February 2019 Senior Management

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[Translator's note: signature]