

Quality and Environment Policy

The **Management** of **Fri.Med. S.r.l.** is determined to maintain and improve the capacity of its structure to supply products at the highest level of competitiveness in the performance/service/price ratio requested by the customer, therefore it places the direct and indirect customer, respect for the environment and staff involvement, at the centre of activities

Fri.Med. S.r.l. is committed to improving its methods and work procedures to arrive, with measurable progress, to providing defect-free products.

An essential tool to achieve this goal is the Management System compliant with **ISO 9001: 2015**, **ISO 14001: 2015** and **ISO 13485: 2016** international standards, which allows to ensure internal efficiency and a better predisposition to meet the needs of customers, while respecting the environment.

Fri.Med. S.r.l. intends to strengthen its presence on the territorial market, by achieving important objectives, ranging from boosting its image, to high-level market knowledge, to the strong awareness that **quality** especially consists, besides the ability to achieve customer satisfaction, while respecting the environment, in the ability to **offer products that can meet the market**, not just the Italian one, but also and above all the foreign one.

The primary commitment of **Fri.Med. S.r.l.** is to provide a product that meets market demands, is high in quality, compliant with customer requirements and applicable production, labelling and CE marking regulations for medical devices, according to MDR 2017/745 (UE) and compliance with general safety and performance requirements (SPR).

The company also undertakes to provide valid support to customers through its dealers, who, with their information, allow the company to best meet customer requirements.

Fri.Med. S.r.l. controls the satisfaction level of its customers, in order to maintain standards and customer focus high.

The careful management of human resources with motivation, development, training and awareness strategy are the essential levers to increase both the competence of the staff and the environmental and quality culture, as well as working in a climate of effective cooperation between all company functions (including customers and suppliers).

Fri.Med. S.r.l. undertakes to designing and developing new products, in line with the market and its evolutions and innovations, as well as with its competitors. To this end, the company participates in trade fairs, in order to expand its knowledge of the market and keep up to date with the latest changes.

The Management has identified the following objectives:

1. Ensure the profitability of the invested capital;
2. Create and maintain a company Management System compliant with the UNI EN ISO 13485:2016 standard as a means of managing the company's business to avoid situations of non-compliance with its customers;
3. Prevent and reduce the environmental impacts of its business:
 - manage waste, minimizing its generation and optimizing its recycling;

- use technologies aimed at the continuous improvement of product quality and the environment at economically acceptable costs;
 - activate careful energy consumption monitoring to seize all the opportunities for its reduction;
4. Customer satisfaction:
 - be aware of its customers' needs;
 - develop competence and efficiency during the provision of services;
 - guarantee compliance with applicable regulations;
 - quick delivery times and economic competitiveness;
 - seek to create a constructive and open collaborative relationship;
 5. Ensure the involvement of all company functions as an integral part of the Quality and Environment System:
 - They must guarantee the performance of the tasks assigned to them by following the methodologies provided, aiming at achieving the objectives that the company sets itself;
 - They must develop critical and analytical skills and improve their work by controlling their activities and promptly adopting corrective actions;
 - Disseminate the results achieved and the critical points to be improved, through information meetings, so as to increase the collaboration of staff to constantly improve the company's quality and the environmental aspects;
 - Increase their motivation also by constantly training and developing all the staff, of any level, who have a working role and directly or indirectly influence the quality of processes and services;
 - Share the stages and structure of managing quality and the environment with its employees so they can participate and be informed about the procedures and benefits brought by implementing this system.
 6. Guarantee, through controlling processes and final testing, a reliable system that meets the requirements expressed by the Customer, those of the applicable regulations and of the environment;
 7. Pursue the continuous improvement of its processes through activities based on their identification and measuring.
 8. Reach an excellent level of execution in correspondence with what was commissioned (in terms of precision, repeatability, finish) of the manufactured products;
 9. Guarantee product traceability, particularly medical devices;
 10. Analyse the risks and opportunities to which the company is subjected, in addition to the market in which it operates and the competitors, in such a way as to best manage the possible interferences and issues, before they arise.
 11. Select its suppliers so that they are able to guarantee high-quality products, as well as compliance with applicable regulations.
 12. Achieve continuous improvement in the quality of the products and services provided, also through collaborating with skilled suppliers, and analysing the market and competitors;
 13. Quantify commitments and objectives to be reviewed each year to check their achievement or to evaluate the deviations and discuss the reasons why they occurred, to implement the appropriate corrective actions or improvement plans.



CORPORATE POLICY: QUALITY AND ENVIRONMENT

LGQA: Attachment 2
of 11/04/2023

The just stated policy, and related objectives, are communicated to all operators by affixing a copy of the document on the company premises, as well as sharing the objectives through periodic meetings with the various functions.

The widest and most frequent involvement of all the employees in this regard is considered an essential requirement by **Fri.Med. S.r.l.**, and ideas and improvement proposals must be favoured at any time during work.

Starting with the needs of the customer and of the market, the Management will therefore define an annual improvement program, specifying the objectives

The Quality and Environment Manager, with the support of the other functions, is responsible for the development, application and revision of the Quality and Environment Guidelines.

Date: 11/04/2023

General Management