MALVESTIO Made in Italy

Makes the difference

Malvestio S.P.A.
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Share capital €2,970,000.00 fully paid up - Padua Chamber of Commerce registration no. 119204
Company registration, tax code and VAT number 00197370281
AEE registration IT22030000013732

QUALITY POLICY

MALVESTIO's senior management is committed to improving its management systems and complying with applicable regulatory requirements, by constantly reminding the entire organisation of the importance of complying with the contractual, legal and regulatory requirements applicable to the processes developed [Medical Devices Regulation (EU) 2017/745, as amended and Decree-Law 137/22, Medical Devices Directive 93/42/EEC-2007/47/EC, NAWI Directive 2014/31/EU, SOLAS 74 Convention, MEDDEV Guidelines, MDCG Guidelines, Regulation (EU) 2023/988 (GPSR), UNI 11780, etc.].

The scope of the management systems has been determined by taking into account internal and external factors (CONTEXT), compliance obligations, interested parties, and the products and services provided by the organisation. The Management System of MALVESTIO SPA (Via Marconi 12/D), covered by the ISO 9001:2015+A1:2024 and ISO 13485:2016 certificates, applies in this case to the following activities:

DESIGN, PRODUCTION, PLACING ON THE MARKET, INSTALLATION AND AFTER SALES SERVICE FOR THE SUPPLY OF FURNITURE AND NON ACTIVE AND ACTIVE, NON INVASIVE MEDICAL DEVICES, FOR PATIENT POSITIONING AND TRANSPORTATION, FOR THE STORAGE OF MEDICINES FOR HOSPITALS, CLINICS, REST HOMES AND OPERATING BLOCKS. DESIGN AND REALIZATION OF MODULAR PANELS, FURNITURE AND ACCESSORIES FOR OPERATING ROOMS AND PREMISES FOR HOSPITAL USE. DESIGN, PRODUCTION, INSTALLATION AND ASSISTANCE OF NON-AUTOMATIC WEIGHING INSTRUMENTS. TRADE OF FURNITURE, EQUIPMENT AND NON ACTIVE AND ACTIVE, NON INVASIVE MEDICAL DEVICES

The same scope of application applies to the Quality Management System in accordance with Article 10 of the MDR (EU) 2017/745, as amended.

In addition to the scope of the Certificate ISO 9001:2015+A1:2024 , the following activities:

PROCEDURES FOR WEIGHING ACTIVITIES FOR THE DETERMINATION OF THE "VERIFIED GROSS MASS OF THE CONTAINER" (VGM) ACCORDING TO METHOD 2 AS PROVIDED FOR IN THE AMENDMENTS TO CHAPTER VI RULE 2 OF SOLAS 74 CONVENTION AS AMENDED

The activities of MALVESTIO SPA, Via Caltana 121, relating to:

REALIZATION OF WALLS, FURNISHINGS AND ACCESSORIES FOR OPERATING ROOMS AND HOSPITAL FACILITIES. PRODUCTION OF HPL LAMINATE COMPONENTS (BACKRESTS)

Our mission is to continue to position ourselves as a leading manufacturer in the field of furniture and medical devices for hospitals, care homes, retirement homes and communities, whilst maintaining a strong commitment to growth and improvement.

MALVESTIO is also committed to upholding the Organisation, Management and Control Model, in accordance with Legislative Decree 231/01, together with its Code of Ethics and the certification of an Occupational Health and Safety Management System in compliance with the ISO 45001 :2018 standard.

To this end, it has established this Company Policy, based on measurable objectives and the use of indicators capable of constantly monitoring the system's ability to meet the requirements of the Customer and 'stakeholders' (CONTEXT).

The Company Policy and the framework of annual objectives are communicated within the organisation through meetings involving all staff, so that the content is understood and supported at all levels and by all relevant stakeholders. The Company Policy is displayed on the company premises, published on the website and maintained (documented information).

Systematic management reviews enable the organisation to ascertain:

- whether the objectives have been achieved and whether they remain appropriate and adequate for achieving the defined aims;
- whether the pursuit of continuous improvement in all business processes is being implemented effectively;
- whether the information provided at the relevant levels of the organisation is appropriate to the objectives.

MALVESTIO's senior management believes that the expertise and technical knowledge acquired over time constitute a key competitive advantage in the market and enable adequate control of the organisation's environmental impacts.

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For this reason, MALVESTIO's strategy is to devote every effort to achieving the following general objectives:

- continuous improvement of production;
- reduction of internal costs;
- optimal management of the raw materials warehouse;
- development of new products for customers;
- compliance with mandatory requirements and customer specifications;
- focusing on the acquisition of plant and machinery that utilises the most advanced technologies;
- continuous improvement of the effectiveness of the company's management system.

Customer satisfaction is achieved by offering processes and products tailored to their specific needs, both implicit and explicit, and by monitoring both the technical progress of the product and the achievement of established competitiveness targets.

MALVESTIO's Senior Management also considers it strategic for the company's development to make the best use of available internal and external human resources in order to build a relationship with customers based on a high degree of trust and reliability, aiming for minimal bureaucracy, a high degree of dynamism and outstanding professionalism. MALVESTIO's Senior Management considers it essential to provide adequate training and awareness-raising for staff to make them aware of aspects relating to the company's activities and enable them to operate in accordance with the requirements of the Management Systems.

To this end, MALVESTIO's senior management provides suitable working environments and the best economically viable technologies to facilitate production activities, and works to establish partnership agreements with suppliers of materials and external contractors.

In order to pursue the overall objectives it has set itself, MALVESTIO's senior management has, as part of a strategic decision, adopted a process-based management approach in accordance with the ISO 9001:2015+A1:2024 and ISO 13485:2016 standards. This approach is aimed at the continuous improvement of the system and the company's performance, based on decisions derived from the analysis of factual data and feedback from the market, obtained in part through maintaining communication with customers and other interested parties.

MALVESTIO's Senior Management is therefore committed to meeting the requirements of the Management Systems and to the continuous improvement of quality performance. By achieving these objectives, the aim is, on the one hand, to create a company strongly focused on its customers, in order to enhance its effectiveness in the market and make customer satisfaction the key differentiating factor in a highly competitive market; and, on the other hand, to be fully aware of its role within the local community.

The Head of Management Systems is directly entrusted by MALVESTIO's Senior Management with the responsibility and authority necessary to ensure that the system is established, implemented and kept up to date in such a way that the entire MALVESTIO organisation is aware of customer requirements, taking all necessary measures to achieve these objectives.

Specific objectives are defined annually as part of the Management Review and communicated to all staff, so that everyone is aware of the importance and relevance of the tasks assigned to them and of how each individual's work contributes to achieving the overall quality objectives.

Furthermore, in 2022, MALVESTIO defined and adopted its SUSTAINABILITY POLICY across three areas: economic, social and environmental.

Malvestio has identified the indicators to be monitored and highlighted the areas for continuous improvement which, over time, will enhance these indicators.

The Quality Policy, including its objectives and the resources made available, is **reviewed** during the Management Systems Review to verify its adequacy and continued suitability to the company's strategies, as well as to identify any necessary changes to ensure it remains appropriate.

MALVESTIO's Senior Management reaffirms the importance of the Management Systems in meeting the requirements of the NAWI Directive and all related regulations, as well as its commitment to providing the necessary resources (human, technological and financial).

Date: 13/05/2026 Legal Representative