

QUALITY MANUAL				
e.janach®	ID doc.	MQ-5 Allegato PQ	Rev	05
	Titolo	QUALITY POLICY	Del	30/05/2025

Quality Policy

E. JANACH S.r.l. as Manufacturer in accordance with the Directive 93/42/EEC and S.M.I. and distributor and importer in accordance with EU Regulation 2017/745 has defined and documented its Quality Policy that establishes, in a manner consistent with the objectives and expectations of customers, objectives and commitments for Quality. In addition, the Quality Policy is oriented to achieving maximum customer satisfaction in compliance with its expectations and needs, thanks to the quality of products and services offered.

The DGE has activated, a program that has as its primary objective the introduction, and subsequently the maintenance updated, of the Quality Management System through a series of written rules that define the operating procedures of the activities carried out and the recognition of compliance with the UNI CEI EN ISO 13485:2021 standard.

Such program allows to introduce in the Staff a new culture, a new mentality oriented to the prevention of the Non-Conformities and to the continuous improvement of the Quality of the supplied products rather than to the control and the correction of the errors committed.

The main objective of the Company is to provide product safety and the search for the best possible working process. In fact, the Company is aware that the Product Safety Guarantee is an essential factor for a company like E. JANACH S.r.l. To this goal are dedicated all the efforts of the company E. JANACH S.r.l. to provide a product of impeccable workmanship, operating in a Quality System able to meet the requirements of the UNI CEI EN ISO 13485:2021, UNI EN ISO 9001:2015 and Directive 93/42 EEC, and subsequent amendments/additions and to EU Regulation 2017/745 for the aspects defined in Art. 120(3).

The improvement of the Company efficiency is another objective that the Management intends to pursue. To this end, it considers that it is essential for this objective:

- ✓ comply with the regulatory obligations laid down by European Directive 93/42/EEC (transposed with D. Lgs. 46/97) and subsequent amendments (e.g. European Directive 2007/47/EC), by EU Regulation 2017/745 for the aspects defined in Art. 120(3) and by UNI CEI EN ISO 13485:2021 and UNI EN ISO 9001:2015, where applicable;
- ✓ have a Quality Management System that, thanks to the collaboration of all the staff can prevent, identify and correct any non-compliance in order to keep it effective and improve it;
- ✓ establish and review specific quality objectives;
- ✓ provide for an adequate and dynamic training plan ensuring a high level of competence;
- ✓ engage with the best companies operating in the sector, in order to pursue continuous improvement;
- ✓ constantly remember that the success of our customers runs parallel to ours;
- ✓ be convinced that our first and irreplaceable resource is people, with their skills and experiences. For our success, we are convinced that it is essential that those who work with us are proud of what they do and why they do it;
- ✓ to bring the principle of continuous improvement into our corporate culture, applying it day by day at a personal and team level.

The valorization of the resources and the motivation of the own Staff are the other objectives that the Company intends to pursue through a program of training and continuous formation on thematic of the Quality and on technical and managerial aspects.

The DGE defines the numerical improvement objectives to be achieved in the activities of individual operators. The objectives defined and the progress of the work to achieve them are analysed in specific meetings. The Management is also committed to promoting the application of the concept of risk-based thinking to plan and implement quality system processes with a view to effectiveness and compliance with mandatory requirements.

This Quality Policy is set out for greater understanding by all staff. The Quality Policy is reviewed during the Management Review (annually) and during the revision of the Quality Manual.

La Direzione

30/05/2025



Negoli. Marco