

	BIOTECHWARE QUALITY POLICY	Rev. 5 of 3 July 2023
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Biotechware S.r.l.'s quality policy is addressed to all patients, users of Biotechware's products and services and to all internal and external stakeholders, in particular staff, suppliers, distributors, business partners, medical organisations and Competent Authorities.

The company uses a Quality Management System that complies with UNI EN ISO 9001:2015 and UNI CEI EN ISO 13485:2021 as an organisational model, so as to constantly monitor and improve the company's performance and consequently its relationship with customers and all stakeholders in general.

Biotechware S.r.l. has always set itself the following objectives:

- health and safety of patients;
- ensure compliance with applicable legal and regulatory requirements for each Medical Device placed on the market;
- implement the relationship with customers and general all stakeholders by creating a relationship based on collaboration, always trying to accommodate and evaluate all requests in order to provide timely answers and adequate solutions;
- adopt an effective approach to risk;
- Preventing and correcting possible problems and non-compliant situations by analysing and reducing the causes that led to deviations between the set and achieved results;
- identify technological innovation needs to develop new products and services according to market expectations;
- identify staff training needs in order to plan training sessions to ensure skills retention and professional growth;
- devote the necessary attention to analysing the customer's needs and reality, so as to ensure a high degree of customer satisfaction;

In particular, the **Top Management** of Biotechware Srl undertakes:

- to support the corporate system with adequate resources and continuous updating of infrastructure and personnel skills so that the above-mentioned initiatives are undertaken and maintained successfully;
- to make the Quality Management System an integral part of corporate life;
- to promote and disseminate the quality policy within the company by means of measurable and monitored objectives over time, in order to constantly update and evolve company strategies;
- to constantly monitor the status of its products and the distribution of its services, intervening if necessary in the event of performance or security-related needs;
- to review this policy to assess whether it is still suitable for the company's needs;
- to ensure that every product placed on the market complies with current legal and regulatory requirements;

The **top management** is aware that the quality policy must be understood, implemented and supported at all levels of the company, and is committed to providing adequate information and involving all personnel, including through:

- giving evidence of the company's quality policy;
- communications and up-to-date information;
- setting quality objectives and supporting their pursuit with appropriate means;
- the promotion of initiatives aimed at gathering suggestions from all staff to improve customer satisfaction, internal safety and environmental protection;
- the activation of training courses on the concepts and application aspects of Quality in Medical Devices and the UNI EN ISO 9001:2015 and UNI CEI EN ISO 13485:2021 standards.

Biotechware treats information with care: we guarantee the utmost confidentiality and integrity of the personal data of customers, suppliers and partners, fully complying with the relevant legal regulations, such as the Data Protection Regulation 2016/679 GDPR.

We work to control and prevent cyber risks by continuously monitoring and updating our technical and organisational infrastructure.

The CEO

Fabrizio Folco