CORPORATE QUALITY POLICY

The General Management of BIOTECK S.p.A. is committed to a process of Quality system management at every level of the company in compliance with the requirements of the UNI CEI EN ISO 13485 standard and the relevant guidelines.
The main objectives are:

- the fulfillment, maintenance and improvement of regulatory requirements, both product and system-related;
- The satisfaction of customers and their requirements;
- the creation of a corporate culture oriented toward continuous improvement;
- the continuous improvement of performance and its effectiveness;
- the full achievement of customer and other stakeholders' (Owners, Employees, Suppliers, Company) satisfaction;
- Respecting and protecting patient health by providing medical devices that provide benefit. The devices supplied are made with continuously updated technologies and according to the latest scientific research;
- Respect environmental and occupational safety aspects;
- **To comply, in the manufacture of its medical devices, with the Essential Requirements of Annex I of Legislative Decree February 24, 1997 - n. 46 "Implementation of Directive 93/42/EEC, concerning medical devices" as amended and supplemented, as well as the provisions of EU Regulation 2017/745 in particular Article 120 thereof for the so-called Legacy devices;**
- **To comply in the manufacture and placing on the market of devices with the requirements of Reg. EU 2017/745 where manufactured, marked and placed on the market according to MDR;**
- **To ensure, in the application of its Quality System, the conformity of its products to the type described in the applied CE certification certificate;**
- give evidence at the Customers of the quality of the products through a proper communication that ensures the positive image of BIOTECK S.p.A. and that complies and is consistent with what is regulated by Reg. EU 2017/745.

Communication pay attention to:

- congresses (popular scientific communication);
- training (formative scientific-commercial communication);
- scientific publications and scientific studies (informative scientific communication);
- collaboration on research activities (developmental scientific communication);
- Gathering feedback from customers to check the possibility of activating improvement actions;
- adequately handle customer complaints in a timely manner;
- periodically verify relationships including partnerships with its suppliers.

The General Management therefore aims to:

- communicate within its organization the quality policy;
- increase prevention activities in order to decrease the costs of non-quality, given by customer complaints through corrective and preventive actions;
- optimize management processes in order to increase the company's competitiveness;
- optimize decision-making processes in order to make them fast and supportive of set goals;
- monitor product compliance through appropriate tools and indicators established during management review;
- use competent and knowledgeable personnel.
- To pay attention to environmental aspects of occupational health and safety.

To this end, a Quality Plan defining the objectives of BIOTECK S.p.A. is prepared and reviewed annually, and the Quality Policy is also reviewed here to ascertain its suitability.
It is the intention of the General Management to ensure that what has been described is fully complied with by every company function involved with product and service quality and that the actions to be taken are implemented and aimed at ensuring at all times the control of processes, product performance, in accordance with the commitments made.

September 01, 2021

BIOTECK S.p.A.
the Executive Board