BIOTECK®
INNOVATING BIOMATERIALS

COMPANY QUALITY POLICY

BIOTECK's Management is committed to implementing the process of managing the Quality system at all levels in the company, in compliance with the requirements of the UNI CEI EN ISO 13485 Standard and of Reg. EU 745/2017.

The main objectives are:

- meeting, maintaining and improving on normative requirements, in terms of both the product and system
- ensuring customer satisfaction and meeting regulatory requirements
- creating a corporate culture focused on continuous improvement of device safety and effectiveness
- continuous improvement of performance and its effectiveness
- fully achieving customer satisfaction and that of other stakeholders (owners, employees, suppliers, companies)
- respecting and protecting the health of the patient, by supplying medical devices that bring benefits. The devices supplied are made using continuously updated technologies and produced based on information provided by the most advanced scientific research
- complying in the manufacture of its medical devices with the Essential Requirements of Annex I of Legislative Decree No. 46 of 24 February 1997 "Implementation of Directive 93/42/EEC, concerning medical devices" as amended and supplemented, as well as the provisions of Regulation EU 2017/745 in particular Article 120 thereof for so-called Legacy Devices;
- complying in the manufacture and placing on the market of devices with the requirements of Reg. EU 2017/745 and subsequent amendments and/ or implementations and/or application interpretations where manufactured, marked and placed on the market according to the MDR;
- ensuring, in the application of its Quality System, conformity of its products with the type described in the applicable CE certification certificate; highlighting product quality with Customers through proper communication that ensures the positive image of BIOTECK and that complies and is consistent with the requirements of Reg. EU 2017/745.

Customer communication is implemented through:

- CONVENTIONS - CONFERENCES (scientific communication for dissemination purposes)
- TRAINING (scientific-commercial training communication)
- SCIENTIFIC STUDIES AND PUBLICATIONS (scientific communication for informational purposes)
- COLLABORATION AND RESEARCH ACTIVITIES (scientific communication for development purposes)

The Management therefore proposes to:

- make the Quality Policy known throughout the organization
- monitor product compliance, its effectiveness and safety through appropriate tools and indicators
- deploy competent and aware personnel
- increase preventive activities in order to decrease non-quality costs, through corrective and preventive actions
- optimize management processes in order to increase company competitiveness
- optimize decision-making processes in order to streamline them and make them effective in supporting the set objectives

To this end, in the annual Management Review, a Quality Plan is prepared, defining BIOTECK's objectives (Quality Plan/Objectives), together with the review of the Quality Policy to ensure its suitability.

The Management undertakes to ensure that this Manual's contents are complied with in full by every company function involved with the quality, safety and effectiveness of the product and service and that the actions to be taken are implemented and designed to ensure that processes and product performance are controlled at all times in conformity with the commitments made.

02 April 2024

BIOTECK S.p.A.
The Management

IMQ CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 13485:2016

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