INTEGRATED MANAGEMENT SYSTEM MANUAL



INTEGRATED MANUAL

Document: 1M Version: 8.0 Page. 1 of 1

ANNEX II: INTEGRATED POLICY

BATEC MOBILITY SL is a manufacturer in the sector of technical aids for people with disabilities (orthopaedic products and wheelchairs). Its main product is the BATEC HANDBIKE, devices that can be attached to manual wheelchairs to revolutionise the mobility of people with disabilities.

In this context, the company has adopted the following integrated policy:

- 1. The quality of the product and the service offered to the customer and the end user is the result of planned and systematic actions of planning, risk management, implementation, verification, continuous improvement throughout the life cycle of the product, aimed at reducing the environmental impact of our operations and establishing actions to protect the physical, mental and emotional health and safety of the people involved in the value chain, including their psychological and social well-being.
- The company's social project, contractual requirements, customer requirements and the wishes and expectations of users, as well as the regulatory requirements for medical devices, environmental management and occupational risk prevention are the criteria for setting the quality standard of our products and services.
- The Managing Director of the company is responsible for driving the implementation, commitment, and determination of objectives for quality, environmental and health and safety management, the review of the Integrated Management System and ensuring the availability of resources.
- 4. Quality, environment and health and safety is a common task for all company processes. Each of them must assume that it is a customer and supplier of the other processes and people in the company. Each employee is responsible for the correct performance of his or her work.
- 5. The application of this Policy requires the active integration of all the company's human resources. To this end, the Management considers the Motivation, Training and Education of the company's staff to be a priority.
- 6. Compliance with quality management standards in the medical devices sector based on EN ISO 13485:2016, Regulation (EU) 2017/745 on Medical Devices (MDR), compliance with EN ISO 14001:2015 and ISO 45001:2018 and all current legislation and regulations on environmental and health and safety matters and current legislation applicable in each territory where our products are marketed.
- 7. The Management appoints the Responsible Technician/PRRC/Quality Manager of the company as the management representative for the tasks of:
 - Ensuring that the necessary processes for the Integrated Management System are established, implemented, and maintained.
 - Reporting to the Managing Director on the performance of the system and any need for improvement.
 - Ensuring awareness of regulatory and customer requirements throughout the company.

In Sant Quirze del Vallès, 4 March 2024

Joan Vidal
MANAGING DIRECTOR
BATEC MOBILITY SL