

Quality Policy

Bit&Brain Technologies S.L., hereinafter Bitbrain, a company dedicated to, on the one hand, the **design of** electroencephalography, polysomnography and pulse oximetry **medical devices** for diagnosis, prevention, monitoring, prediction, prognosis, treatment or relief of neurological diseases, such as dementia, Alzheimer's, Parkinson's, epilepsy, or stroke among others, **according to UNE EN ISO 13485** and, on the other hand; to the design, manufacture, sale and technical assistance of products for research, monitoring, understanding and improvement of human health, and in accordance with the regulatory requirements of **Regulation (EU) No. 2017/745 on medical devices**, declares that:

Bitbrain's management will drive quality as a main objective of the company. Therefore, Bitbrain's management is committed to providing the necessary resources foreseen to meet these quality objectives, as well as regulatory and customer requirements.

Continuous improvement in all processes, products, and services of the company will be established as a key objective to achieve the satisfaction of customers and employees and ensure the future of the company.

Bitbrain's management will promote a process approach and risk-based thinking, to ensure that risks and opportunities that may affect the conformity of products and services and the ability to improve customer satisfaction are identified and considered.

To successfully address our path to excellence, we identify our purpose within the market and society, the goals we expect to achieve and the values we must develop in order to get there. Bitbrain's Quality System will comply with the requirements of the UNE EN ISO 13485 standard, which will be certified in an accredited manner.

Maintaining the certification is considered a general objective. Each year, Bitbrain's Management Board will set general objectives that are measurable and consistent with its strategy.

Based on these objectives and considering those that affect the Quality field, Bitbrain's Quality department will develop and analyze their compliance, and will establish plans and resources to achieve them.

Bitbrain Management Board will ensure that responsibilities and authorities within the organization are defined and communicated.

The Bitbrain Management Board will appoint the Quality Manager as a representative of the Management, and will delegate to them the authority to assess, recommend and initiate the necessary actions to ensure that the Quality System is in accordance with standard UNE EN ISO 13485, and that it is applied, retained, and continuously improved.

This policy will be shared and communicated to our employees and interested parties to motivate them in their commitment to the clients, to the company and to the quality of our services.

This policy will be continually adapted, updated and reviewed by Bitbrain management.



Signed by: María López Valdés, CEO of Bit&Brain Technologies S.L.