QUALITY POLICY

Healthsens is recognized by the Asociación Nacional de CEEI Españoles (ANCES) as an innovative technology-based company (EIBT), whose activity is focused on the development, production and commercialization of biomarker-detection systems for pathologies highly prevalent in the world´s population.

Its mission is to provide its clients and collaborators with innovative and easy-to-use tools that perform precise measurements at an excellent quality-price ratio, enabling early diagnosis and/or monitoring of disease evolution. The goal is to become a leading company in the biomedical sector in the development of fast and portable biomarker-detection systems, also known as self-testing devices.

The pillars that constitute Healthsens foundations are:

- The close collaboration with Hospitals and Asturian University Institutions in R&D activities.
- The in vitro diagnostic medical devices and services provided to our customers are designed to be safe, reliable and comply with applicable specifications, standards and legislation.
- The close relationship with our interest groups, analyzing exhaustively their needs and expectations to provide them with a prestigious service.
- The achievement of excellent working environment and conditions that ensure the wellbeing and satisfaction of the multidisciplinary team that forms Healthsens.
- The commitment to comply with applicable legal and regulatory requirements.
- The commitment to maintain the effectiveness of the quality management system.
- The purpose to improve the quality of the medical devices and services we deliver using data analysis to identify possible areas of improvement, in collaboration with other interest groups involved.

We pursue a continuous improvement of our processes and the maintenance of a Quality Management System in accordance with the requirements established by the UNE-EN ISO 9001 (Quality Management Systems, Requirements), the UNE-EN ISO 13485 standard (Medical Devices, Quality Management Systems, Requirements for regulatory purposes), the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, and European Regulation 2017/746 IVDR.

This quality policy is reviewed at least once a year and provides the reference framework for defining and updating the objectives of the quality management system.

Oviedo, Asturias. October 14, 2022.

Iván Rodríguez Merás

Managing Director

Olaya Amor Gutiérrez

R&D Director