Our Quality Policy

The three foundations of our Company, that are at the heart of every of our activities are:

OUR VISION[1]	**OUR MISSION**[2]
As life expectancy increases, there will be need for enhancing people Quality of Life globally, by preserving, restoring and protecting their autonomy and independence, while reducing carbon footprint on our planet.	*Conceive, develop, validate, and bring to market innovative, science-driven and eco-friendly technological solutions allowing adults and seniors to enhance their physical, emotional and cognitive status.*

OUR VALUES

- *Intuition (*research and enthusiasm at the basis of all our action*)*
- *Planning (*every idea, if not transformed into a project, will be unfruitful*)*
- *Exchange of ideas (*sharing of goals to get them*)*
- *Method (*pursuit the excellence*)*
- *Adherence (*commitment in doing*)*
- *Result and* ***Quality***

The inclination at pursuing the Quality[3] is an intrinsic part of our company behaviour, that defines specifically our:

QUALITY GOAL

consistently design, manufacture and market medical devices and related services that comply with interested parties' requirements, meet and aim at exceeding their needs and expectations, ensure patient safety and efficient customer care and technical assistance, as well as effectiveness and excellence in the products and services offered.

Where:

- our interested parties are **our customers and regulatory bodies/authorities**. Our policy is therefore based on their requirements, needs, expectations.
- our business objectives lead us to aspire to become a stable and reliable provider of technologies in the healthcare sector, in medical device industry specifically.

This quality policy is our framework for setting our Quality Goal in our Quality Management System (QMS). The quality objectives are instead the method by which we translate this goal into plans for maintain and continuously improve the effectiveness and excellence of our QMS. We then set our:

[1] The Vision of an organization describes the desired state that the organization wants to achieve: its general goals.

[2] The Mission of an organization refers to its purpose and describes why the organization exists, who it serves, and so on.

[3] Definition from ISO9000-2015: *degree to which a set of inherent characteristics fulfils requirement*.

QUALITY OBJECTIVES[4]

Compliance Assurance	Ensure adherence to ISO 13485 standards and relevant regulatory requirements throughout all stages of the product lifecycle.
Product Design Excellence	Continuously improve product design processes to enhance device reliability, safety, and performance, fully meeting stakeholder's requirements.
Production Efficiency	Optimize manufacturing processes to ensure consistent product quality and on-time delivery.
Customer and User Satisfaction	Solicit feedback from customers and users to identify areas for improvement and enhance overall satisfaction with products and services. Provide timely and effective technical assistance to customers, addressing inquiries, troubleshooting issues, and resolving product-related problems.
Continuous Improvement	Foster a culture of continuous improvement by promoting employee engagement, training, and empowerment.

This Quality Policy then defines the areas and scope in which the Quality Management System (QMS) and its planned activities will be active and valid. Our quality policy is then applicable to all activities that are included under the QMS and all roles in the supply chain for our medical products. Our QMS is based upon **ISO 13485:2016/A11:2021**, regulatory (**EU Reg 2017/745**, specifically refer to Art 10 for QMS) and our **customers' requirements**.

Through regular audits and management reviews**,** we are committed to ensuring compliance with all these requirements, and where appropriate, to continually improving the effectiveness of the QMS in meeting our quality objectives. The management is committed to provide the staff with continuous training, to maintain and improve our managerial and technical skills, communicate, and remind HENESIS quality policy to all employees regularly, through dedicated newsletters and meetings. This quality policy and the corresponding objectives are always accessible to all employees in the HENESIS' website and online shared folders.

Date 03/09/2024

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Name and Function

Luca Ascari, Director

Signature

Luca Ascari

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[4] Additional details can be found in QPO002 (latest version)