



**france
hopital**

Management commitment - Quality and Environment Policy

The management of FRANCEHOPITAL, through the adoption of **UNI CEI EN ISO 13485:2021 and UNI EN ISO 9001:2015** quality management systems, is committed to providing high-quality products and services. This ensures the safe and effective design, production, and distribution of medical devices, in line with the latest industry regulations. Additionally, by adopting the **UNI EN ISO 14001** environmental system, the company places particular emphasis on the environment.

Our company is dedicated to creating an inclusive and respectful work environment where every individual, regardless of gender, can reach their full potential. We actively promote gender equality, guaranteeing equal opportunities at all levels and working to achieve a balanced representation of women and men in all positions.

The integration of various systems makes management simple and flexible, allowing for continuous application and improvement by all personnel.

The principles that inspire FRANCEHOPITAL and form the basis of its quality policy are:

- Reliability, seriousness, and ethics;
- End-user and/or patient safety;
- Regulatory compliance;
- Product quality;
- Innovation and efficiency;
- Competence and professionalism of the personnel employed;
- Constant search for the best way to work with the aim of satisfying the requirements of the reference standard and regulations;
- Continuous improvement of the effectiveness of the quality management system;
- Pursuit of customer satisfaction.

FRANCEHOPITAL management, in its daily activities, both domestically and internationally, is aware of operating within a specific context and for this reason is committed to analyzing it and promptly identifying changes.

Similarly, it is aware of acting with different stakeholders, with different interests that need to be satisfied. For these reasons, it feels the need to ask for the support of all the actors who are at the basis of its approach, and in particular:

- The Quality and Environmental Management System Manager (RSGQA) to keep the system alive, monitor it, and continuously adapt it, and to make it known;
- The Management Representative (MR) to ensure that the management system is implemented, maintained, and promoted within the organization;
- Each FRANCEHOPITAL employee to implement all the provisions of the Quality Management System, ensuring the achievement of the set objectives;
- Our partners and suppliers so that, through knowledge of the Quality and Environmental Management System, they can also adapt and improve their performance, both in terms of quality and the environment;
- Our customers because their needs and expectations must be at the center of the management system.

Starting from the analysis of its context and the needs of the different stakeholders, FRANCEHOPITAL management is committed to identifying and assessing risks:

- That could reduce the effectiveness and efficiency of its actions and activities;
- That could expose the Quality and Environmental Management System to conditioning and criticalities.

To this end, it takes charge of the best possible management of risk factors.

FRANCEHOPITAL SAS

Z.I. Ouest, 27 Rue Georges Besse – F-67151 Erstein Cedex / FRANCE - SAS au capital de 36 000€ - RC Strasbourg B 348 139 882
Sede Secondaria Italiana 39011 Lana - Bolzano, Zona Industriale 11 - **Centro Logistico** 25012 Malpaga di Calvisano (BS), Via A. Vivaldi 3
www.francehopital.com





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FRANCEHOPITAL management is firmly convinced that achieving the following objectives is fundamental to the company's success:

- **Patient safety:** Putting patient safety first, ensuring that our medical devices are designed, produced, and distributed in a way that minimizes health risks.
- **Regulatory compliance:** Ensuring full compliance with all applicable regulations for medical devices, including European directives and national and international regulations.
- **Product quality:** Guaranteeing the quality of our products at every stage of the life cycle, from design to distribution, through the application of controlled processes and the use of high-quality materials.
- **Customer satisfaction:** Satisfying the needs and expectations of our customers, providing high-quality products and services and guaranteeing their satisfaction.
- **Continuous improvement:** Promoting continuous improvement of our processes and products, through data analysis, identification of non-conformities, and implementation of corrective and preventive actions.
- **Personnel involvement:** Involving all personnel in a systematic approach to quality, providing the training and resources necessary to carry out their activities effectively.
- **Suppliers:** Carefully selecting and evaluating suppliers, ensuring that they provide products and services that comply with our quality requirements.

To achieve the above objectives, the company undertakes to:

- Define and document processes;
- Establish measurable quality objectives;
- Conduct internal audits;
- Analyze data to identify areas for improvement;
- Implement corrective and preventive actions;
- Share the quality policy with all stakeholders

The periodic Management Review will allow us to analyze the objectives and make any necessary adjustments.

FRANCEHOPITAL management is committed to respecting, verifying, and updating the Quality and Environmental Management System.

Gunnar PERONI

President

Lidia VASCON

Vice-President

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