Assut Europe S.p.A., a manufacturer of Medical Devices, considers it is essential to provide high quality products that comply with the intended use, in an efficient and safe manner.
Assut Europe General Management has established the following quality policy:
meet regulatory requirements and customer requests, providing high quality products and services, but reducing costs.
Assut Europe is committed to meeting the requirements of the standards:

- UNI EN ISO 9001:2015
- UNI EN ISO 13485:2016
- UNI/PdR 125:2022
- European Directive 93/42/EEC, as amended
- Regulation (UE) 2023/607
- MDR 2017/745
- QSR 21 CFR 820
- RDC 665 (Anvisa)
- Ukranian Regulation n° 753/2013

and to maintain an efficient QMS that complies with the aforementioned standards.

**Quality objectives:**

- place high quality products on the market
- improve internal organization and optimize the resources
- improve control over finished products
- improve the reliability of procurement
- profitably paricipate in tenders
- achieve customer satisfaction

To achieve the desired objectives, it is necessary to:

- minimize any cause of errors, any shortcoming and any non-compliance, using adequate formal procedures
- ensure that the employees hold the qualification, experience and training required to perform their tasks satisfactorily
- make the necessary infrastructures and resources available
- ensure that suppliers are qualified
- identify, record and solve any non-compliance using adequate formal procedures
- ensure the continuous improvement of business processes through every possible information coming from market analyses
- assess risks and opportunities associated with business processes

**Scope and Quality objectives for Gender Equality:**
Assut Europe intends to ensure gender equality relating to equitable professional growth within the company.
In this sense, it wants to proceed with the valorization of the diversity present in the roles that operate in the organization and to maintain processes capable of developing female empowerment in business activities.
The organization's attention, in the path that ensures the achievement and maintenance of this purpose, focuses its efforts in the following areas prepared by the UNI PDR 125:2022:

1. Culture and strategy
2. Governance
3. HR processes
4. Opportunity
5. Reward equity
6. Parenting

Assut Europe believes that the development of a cultural model that promotes gender equality, in addition to generating "social value" appreciated in the national and European institutional economic context, constitutes a development factor for the business that the organization conducts.

**Results based on stakeholder satisfaction for Gender Equality:**

Assut intends to ensure gender equality through concrete actions which, in addition to being compliant with the requirements and indicators established in the individual areas indicated, result in real and concrete appreciation by the women present in the organization, who are the real interested parties, in the results that the management system produces.

The organization, with the desire to pay attention to this satisfaction at any time and in any circumstance of the working life of the woman in the organization, has chosen to look at this "life cycle" through the following aspects:

- Selection and hiring (recruitment)
- Career management
- Pay equity
- Parenting, care
- Work-life balance
- Prevention of abuse and harassment

For each of the previous aspects, Assut has established a "technical policy" where the principles that inspire the organization are defined and to which specific and measurable equality objectives indicated in the strategic plan are associated, and defines the method of access to these aspects for male and female workers.

Assut, in relation to the analysis of its business processes, has understood and established the principles to be respected in reference to each of the following points. These principles constitute the inspiring criteria of the processes aimed at addressing:

- The existing gaps in reference to the indicators established by the UNI PdR 125:2022
- The needs of women present in the organization, seen as the main interested parties

concrete results of the system

**The main characteristics of the company Quality System are:**

- a rigorous program of internal audits
- a corrective and preventive actions implementing procedure
- a documented system

**Evolution of business culture towards company's continuous improvement and total quality**

For this purpose, Assut Europe S.p.A., involving all the employees, has set up a Quality System which is implementes from the design of medical devices to post-market surveillance.

To achieve the aforementioned objectives, the General Management undertakes to:

- plan improvement strategies

- involve all the personnel through constant information and training, also optimizing response times to change
- involve all customers by collecting and examining their complaints, needs and proposals
- set up an organizational structure aimed at implementing what established
- provide the necessary infrastructure, human and instrumental resources
- monitor the implementation of Quality Manual content
- periodically check the compliance of the system with the company policy and make the organizational and technical changes necessary to pursue this objective

**Assut Europe S.p.A General Management,** aware that quality policy must be understood, implemented and supported at all business levels, undertakes to provide adequate information and to involve the whole personnel also through:

- promoting company policy for quality
- establishing a code of ethics
- communications and updated information displayed on the company bulletin board
- setting qualitative objectives and supporting their pursuit with adequate means
- promoting initiatives aimed at collecting suggestions from the personnel and aimed at improving customer satisfaction, internal security and environmental protection
- the activation of training courses on the concepts and the implementation aspects of Total Quality, the legal provisions on medical devices, the standards UNI EN ISO 9001, 13485 and 14001, UNI PdR 125:2022, QSR 21 CFR 820, RDC 665 (Anvisa) and Ukranian Regulation n°753/2013.

**Magliano Dei Marsi, 09.01.2024**

ASSUT EUROPE SpA
Direttore di Stabilimento
Sandro Di Nardo