Aferetica Srl's policy is to create, validate and promote the use of Apheretic Therapies in numerous clinical settings, through the design, development and marketing of complete therapeutic systems. In particular, in the field of transplantation, Aferetica creates solutions for organ management (ex-situ reconditioning), designing integrated systems for storage and treatment with transport and support modules.

All systems designed, developed and marketed by Aferetica must:

- **Comply with the mandatory requirements**: Compliance with the General Safety and Performance Requirements of **Regulation (EU) 2017/745 (MDR)** and the Essential Requirements of DDM 93/42/EEC (for legacy devices pursuant to EU Reg. 2023/607).
- **Ensuring access to international markets**: Compliance with regulatory requirements for marketing in:
  - Switzerland (**MedDO SR 812.213**)
  - United Kingdom (**UK MDR 2002**)
  - Extra-EU: including Brazil (**ANVISA)**
- **Satisfy stakeholders**: Meet expectations of clinical efficacy, functionality and ease of use for users.
- **Integrate the climate variable (ISO 9001:2015+A1:2024):** In line with the evolving global context, Aferetica is committed to assessing the risks arising from **climate change** at every stage of the product life cycle. The strategy aims to ensure supply chain resilience and device integrity against extreme environmental variables, promoting sustainability for patients and healthcare facilities.

Aferetica collaborates with Research Centers and Universities for the technological and clinical development of new medical devices.

THESE REQUIREMENTS MUST BE TRANSFORMED INTO OBJECTIVES AT ALL LEVELS OF SOCIETY AND MONITORED

This Policy is implemented through the activities that Aferetica Srl considers strategic in order to guarantee the quality of the product/service and which are listed below:

1. **Integrated Management System**: Organized to meet the requirements of Regulation (EU) 2017/745, the Swiss MedDO, UK MDR 2002, the national regulations of the target markets (e.g. Brazil) and the **UNI CEI EN ISO 13485:2021** and **UNI EN ISO 9001:2015 standards (including the Amendement A1:2024).**
2. **Collaboration with Suppliers**: Design and production processes are planned with qualified suppliers to ensure safety, quality and compliance with applicable product standards.
3. **Continuous Improvement and Risk Analysis**: The Management System activates corrective and preventive actions to monitor critical processes. All business processes are managed according to a rigorous *risk management approach*.
4. **After-Sales and Safety**: Planning of all after-sales technical assistance and post-market surveillance activities to ensure maximum safety for the user and the patient in each geographical market of presence.

San Giovanni in Persiceto, 28/04/2026

The General Management
Dr. Mauro Atti

