

Aferetica Srl's policy is to create, validate and promote the use of Apheretic Therapies in several clinical areas, through the design, development and promotion of complete therapeutic systems.

In particular, in the field of transplantation, Aferetica creates solutions for ex-situ organ reconditioning. Aferetica designs, develops and creates integrated systems for organ preservation and treatment, with transport and support modules.

All systems designed, developed and promoted by Aferetica must

⇒ Be compliant to comply with the General Safety and Performance Requirements of Regulation (EU) 2017/745, the Essential Requirements of the MDD 93/42/EEC (implemented in Italy by Legislative Decree 46/97) as amended by Directive 2007/47/EC (implemented in Italy by Legislative Decree 37/2010) (only for legacy devices benefiting from the extension under Regulation (EU) 2023/607), the Medical Devices Ordinance SR 812.213 (MedDO), and Resolution No. 753 of the Cabinet of Ministers of Ukraine dated 2 October 2013;

⇒ as well as the requirements of the applicable specific standards, and the requirements of the standards applicable to the medical sector and to the processes managed within the company;

Aferetica Srl collaborates with Research and University Centers for the technological and clinical development of new medical devices in order to meet users' needs in relation to the features listed in the previous point.

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

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

⇒ ⊗ *The company's Quality Management System is organized to meet the requirements of the MDD 93/42/EEC (and subsequent amendments) with respect to legacy devices benefiting from the extension under Regulation (EU) 2023/607, Regulation (EU) 2017/745, the Medical Devices Ordinance SR 812.213 (MedDO), Resolution No. 753 of the Cabinet of Ministers of Ukraine dated 2 October 2013, and the standards UNI CEI EN ISO 13485:2021 and UNI EN ISO 9001:2015;*

⇒ *The design, the development and the production processes are planned with the close collaboration of qualified Suppliers in outsourcing in order to guarantee the quality and safety of the medical devices manufactured and the compliance with the mandatory requirements of the directives and applicable product standards;*

⇒ *The Quality Management System is organized to activate suitable corrective and preventive actions in order to guarantee the maintenance of its effectiveness and to monitor the critical aspects for the warranty of the adequacy of the company's processes, the medical devices and the service to the market's and the users' needs and their compliance with the applicable standards and directives. All production processes are managed according to a risk management approach;*

⇒ *Among the company's processes there is also the planning of all post-market technical assistance to ensure user's and patient's safety.*

San Giovanni in Persiceto, 03/06/2024

General Manager
Dr. Mauro Atti