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 in-situ and/or ex vivo organ reconditioning. Aferetica designs, developes 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 with the Essential Requirements of the DDM 93/42/EEC (introduced in Italy with Legislative Decree 46/97) amended by Dir. 2007/47 (and introduced in Italy with Legislative Decree 37/2010), to the transitional provisions of article 120 of Regulation (EU) 2017/745 as well as the requirements of the standards applicable to the medical field and to the company's processes;

- ⇨ Meet users' needs and requirements in terms of clinical effectiveness, functionality, performance, ease of use;

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 Quality Management System is organized to meet the requirements of the DDM 93/42/EEC (and subsequent updates) and the transitional provisions of article 120 of Regulation (EU) 2017/745 and the UNI CEI EN ISO 13485:2016 and UNI EN ISO 9001:2015 standards;*

- *The design, the development and the production processes are planned with the close collaboration of qualified Suppliers in outsoursing 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 procesess there is also the planning of all post-market technical assistance to ensure user's and patient's safety.*

San Giovanni in Persiceto, 29/09/2022

General Manager
Dr. Mauro Atti