

No. A18146 / 12.11.2023

To: „CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE”**Address:** 22/2 Grigore Vieru Boulevard, ZIP 2005, Chisinau, Republic of Moldova**Subject:** Confirmation of Compliance with Tender Requirements - Tender Code: ocds-b3wdp1-MD-1697197092594

To whom it may concern,

We, Fresenius-Kabi, hereby confirm that our consumable „Apheresis Kit” (Product Code: **R6R8884**) is compatible with the **AmiCORE** Device (Product code: **6R8800**) and meets the minimum requirements specified in the tender with the code "*ocds-b3wdp1-MD-1697197092594*" and the tender name "*Achiziționarea reactive și consumabile medicale întru realizarea Programului Național „Securitatea transfuzională și autoasigurarea țării cu produse sanguine” conform necesităților pentru anul 2024*".

The consumable kit has been specifically designed and developed to fulfill the technical specifications outlined in the tender. The kit comprises the following components with the specified properties: AmiCore Platelets Kit (R6R8884) + ACDA Solution (TS14015) and is compatible with the AmiCORE Device offered in the tender.

The kit is intended for the collection of platelets and plasma in the specified doses.

The kit for the collection of double dose of platelets and one dose of plasma and meets the following technical specifications:

1) Mandatory components of the set:

- a) Base materials of plastic - polyvinyl chloride.
- b) Technology ensuring leukocyte reduction to obtain the finished product without leukocyte contamination.
- c) AC needle type 17 G with a lateral fissure.
- d) Post-donation needle cap system for subsequent harmless use.

2) Anticoagulant solution:

- a) Plastic container.
- b) Volume of 500 ml.
- c) Sterile and pyrogen-free.
- d) Equipped with an element for securing the container in a holder.
- e) Contains citrate and dextrose.

3) Laboratory blood sampling system:

- a) Vacuum tube holder and needle.
- b) Integrated into the closed and sterile collection tubing system.
- c) Equipped with a clamp.

4) Container for platelet collection and storage:

- a) The consumable kit contains 2 containers for platelets.
- b) Allows for the collection of two doses of platelets from the donor.
- c) Upper connection port for connection to the transfusion system.

- d) Lower slot for suspending the container in the transfusion holder.
- 5) The platelet collection set is equipped with a reservoir/vial for collecting platelet samples for quality control examination, with a maximum capacity of 10 ml.
- 6) Container for plasma collection and storage:
- a) One container provided.
 - b) Capacity of the plasma bag: 1000 ml.
 - c) Two orifices on the top for securing it in the blood component separation device.
 - d) Upper connection port for connection to the transfusion system.
 - e) Lower slot for suspending the container in the transfusion holder.
 - f) The connection tubing to the anticoagulant solution is equipped with a filter.

Furthermore, as a trusted manufacturer, Fresenius-Kabi ensures that AmiCORE and it's consumables are manufactured using state-of-the-art technology and adheres to the highest industry standards. We have conducted thorough testing and validation processes to ensure its compliance with international standards and we are confident in our solution's ability to contribute to the goals of the National Program "*Securitatea transfuzională și autoasigurarea țării cu produse sanguine.*"

Yours sincerely,
Eugen Calescu
Sales & Application Specialist
MedTech
Fresenius Kabi Romania SRL



Strada Henri Coandă, Nr. 2,
Oraș Ghimbav, Județ Brașov
Cod postal 507075

Cont: RO85RZBR0000060001825567
Raiffeisen Bank Sucursala Brașov

Registrul Comerțului: JO8/487/1993
CUI: 3391027
CIF: RO3391027
Capital social: 2.869.820 lei