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KOKKUPANDAVAD PLASTIKANUMAD INIMVERE JA SELLE KOMPONENTIDE KÄITLEMISEKS. OSA 4: AFEREESIPROTSEDUURIS KASUTATAVAD KOMBINEERITUD OMADUSTEGA VEREKOTISÜSTEEMID

Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features (ISO 3826-4:2015)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 3826-4:2015 sisaldab Euroopa standardi EN ISO 3826-4:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 3826-4:2015 consists of the English text of the European standard EN ISO 3826-4:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.08.2015.	Date of Availability of the European standard is 19.08.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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ICS 11.040.20

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 3826-4

August 2015

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English Version

Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features (ISO 3826-4:2015)

Poches en plastique souple pour le sang et les composants du sang - Partie 4: Systèmes de poches d'aphérèse pour le sang avec accessoires intégrés (ISO 3826-4:2015)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 4: Apherese-Blutbeutelsysteme mit integrierten Merkmalen (ISO 3826-4:2015)

This European Standard was approved by CEN on 23 April 2015.

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European foreword

This document (EN ISO 3826-4:2015) has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use” in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 3826-4:2015 has been approved by CEN as EN ISO 3826-4:2015 without any modification.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated ISO or IEC standard, as listed below.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

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Table — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 594-2	—	ISO 594-2:1998
ISO 1135-4	EN ISO 1135-4:— [a]	ISO 1135-4:— [a]
ISO 3696	EN ISO 3696:1995	ISO 3696:1987
ISO 3826-1	EN ISO 3826-1:2013	ISO 3826-1:2013
ISO 3826-2	EN ISO 3826-2:2008	ISO 3826-2:2008
ISO 3826-3	EN ISO 3826-3:2007	ISO 3826-3:2006
ISO 8536-4	EN ISO 8536-4:2013 and EN ISO 8536-4:2013/A1:2013	ISO 8536-4:2010 and Amd.1:2013
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 plus Amd.1:2006
ISO 10993-5	EN ISO 10993-5:2009	ISO 10993-5:2009
ISO 10993-10	EN ISO 10993-10:2013	ISO 10993-10:2010
ISO 10993-11	EN ISO 10993-11:2009	ISO 10993-11:2006
ISO 10993-12	EN ISO 10993-12:2012	ISO 10993-12:2012
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 15747	EN ISO 15747:2011	ISO 15747:2010
ISO 23908	EN ISO 23908:2013	ISO 23908:2011

[a] To be published.

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Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices

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This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Medical devices

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC / Directive 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on Normative References according to Table of References, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC, Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.2.1, 6.2.3, 6.2.7, 6.2.8, 6.2.9, 6.2.10, 6.2.11, 6.3, 7	7.2	Only the protection to the patients is explicitly addressed. The part of ER 7.2 regarding the packaging is not fully addressed. For packaging, see Clause 7 of this part of EN ISO 3826.
5.1 to 5.8, 6.2, 6.3, 6.4	7.3	Only the first half sentence of ER 7.3 is addressed. ER covered by biological evaluation.
6.2.7, 6.2.10, 6.3, 6.4	7.5 (first and second paragraph)	The part of ER 7.5 relating to phthalates is not explicitly covered. Only the first sentence is covered. Presumption of conformity with the Essential Requirements relating to the biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993 series of standards.

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.3.1, 5.3.3, 5.4, 5.5.1, 5.5.4, 5.9.1, 5.10.3, 5.10.5, 5.11, 6.1, 6.2.1, 6.2.2, 6.2.6, 6.2.7, 6.2.10, 6.2.11, 6.4.2	7.6	
5, 6	8.1	The part of ER 8.1 relating to easy handling is not addressed. Manufacturing processes are not covered. Only sterility of product is covered.
7	8.3	
6.2.1, 6.2.2	8.4	
6.2.1	8.5	
5.8, 5.9, 5.10, 5.11	9.1	Restrictions indicated on the label or in the instructions for use are not addressed.
4, 5.4	9.2	
6.2.7, 6.2.8, 6.2.9, 6.2.10	12.7.1	Only resistance to mechanical stress is addressed.
8.2 to 8.6	13.1	
8.1	13.2	EN ISO 15223-1 and EN ISO 3826-2 are addressed when using symbols.
8.2 to 8.6	13.3	The part of ER 13.3 related to authorized representative is not addressed. 13.3 d) is only covered if the batch number is preceded by the word 'LOT'. 13.3 f) Requirement indication of single use must be consistent across the Community is not addressed in this part of EN ISO 3826. 13.3 g) and h) are not addressed in this part of EN ISO 3826.
8.2 to 8.6	13.4	

WARNING — Other requirements and other EU Directives can be applicable to the product(s) falling within the scope of this part of EN ISO 3826.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

ISO 3826 consists of the following parts, under the general title *Plastics collapsible containers for human blood and blood components*:

— *Part 1: Conventional containers*

— *Part 2: Graphical symbols for use on labels and instruction leaflets*

— *Part 3: Blood bag systems with integrated features*

— *Part 4: Aphaeresis blood bag systems with integrated features*

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Introduction

In some countries, national pharmacopoeias or other government regulations are legally binding and these requirements take precedence over this part of ISO 3826.

The manufacturers of the plastics container or the suppliers are expected to disclose in confidence to the national control authority, if requested by them, full details of the plastics material(s) and the components of the materials and their methods of manufacture, details of manufacture of the plastics containers including the chemical names and quantities of any additives, whether incorporated by the manufacturer of the plastics containers or present in the raw material, as well as full details of any additives that have been used.

Universal leucocyte depletion is mandatory in various countries. This part of ISO 3826 is considered a basic document for other standards which include technical innovations.

The requirements in this part of ISO 3826 are intended to

a) ensure that the quality of blood and blood components is maintained as high as necessary,

b) make possible efficient and safe collection, identification, storage, separation, and transfusion of the contents with special attention to reducing or minimizing the risks resulting from

   — contamination, in particular microbiological contamination,

   — air embolism,

   — errors in identification of plastics containers and any representative samples of contents, and

   — interaction between the plastics container and its contents,

c) ensure functional compatibility when used in combination with transfusion sets as specified in ISO 1135-4 and ISO 1135-5, and

d) provide a package with appropriate resistance to breakage and deterioration.

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Plastics collapsible containers for human blood and blood components —

Part 4: Aphaeresis blood bag systems with integrated features

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1 Scope

This part of ISO 3826 specifies requirements including performance requirements for aphaeresis blood bag systems with integrated features. Aphaeresis blood bag systems need not contain all of the integrated features identified in this part of ISO 3826.

The integrated features refer to:

— needle stick protection device;

— leucocyte filter;

— sterile barrier filter;

— pre-collection sampling device;

— red blood cell storage bag;

— plasma storage bag;

— platelet storage bag;

— polymorphonucleic (e.g. stem) cell storage bag;

— post-collection sampling devices; and

— connections for storage solutions, anticoagulant, and replacement fluid.

This part of ISO 3826 specifies additional requirements for blood bag systems used to collect varying quantities of blood components or cells by apheresis. This part of ISO 3826 can be used on automated or semi-automated blood collection systems.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 3826.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[1)]

ISO 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use*[2)]

1) Will be replaced by ISO 80369-7.

2) Will be split up in two parts of which the revised ISO 1135-4 covers transfusion sets for single use, gravity feed and the new ISO 1135-5 covers transfusion sets for single use with pressure infusion apparatus.

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ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 3826-1, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 3826-2, *Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets*

ISO 3826-3, *Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features*

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15747, *Plastic containers for intravenous injections*

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
aphaeresis (apheresis)
process by which blood being removed from a subject is immediately separated into component parts, usually to allow a desired component or components to be retained while the remainder is returned to the subject

3.2
aphaeresis set
whole aphaeresis blood bag system with integrated features

Note 1 to entry: Can also be called an aphaeresis kit or harness.

3.3
centrifugation
process in which circular motion is applied to a chamber about a central axis such that the fluid contents of the chamber are separated according to density where the most dense is towards the outer circumference of motion and the least dense is towards the inner circumference of motion

3.4
connector
component that allows one part of the set to be connected to another

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3.5
citrate anticoagulant
citrate, in the form of sodium citrate or acid-citrate-dextrose, is added to the blood as it is drawn from the subject's circulation and binds or chelates ionised calcium within the blood, thereby, impeding those steps of the coagulation pathway that are dependent on the presence of ionised calcium

3.6
clamp
device that prevents the flow of fluid through the lumen

Note 1 to entry: These can be locking (permanent) or non-locking (temporary).

3.7
extracorporeal circuit
path followed by whole blood or blood components when they are outside the subject's circulation

3.8
fluid pathway
route along which fluids (whole blood, blood components, ancillary intravenous solutions) pass composed of tubing, chambers, *connectors* (3.4) and pressure sensors, and needles

Note 1 to entry: The fluid pathway is constructed to ensure that the fluid within it remains sterile and to ensure that there are no restrictions or obstructions within it that might result in cellular damage or activation of the coagulation cascade.

3.9
leucocyte filter
filter used to reduce the content of leucocytes in blood or blood components

3.10
pilot sample
sample of unmistakable identity to be used for testing

3.11
plasma
blood plasma is a liquid component of blood

Note 1 to entry: It makes up of about 55 % of total blood volume.

3.12
plastics container
bag of plastic material complete with collecting tube and needle, port(s), anticoagulant and/or preservative solutions, and transfer tube(s) and associated container(s) where applicable

3.13
platelets
platelets or thrombocytes are small, irregularly shaped, clear cells with no nucleus involved in haemostasis leading to the formation of blood clots

3.14
platelet additive solution
PAS
solution in which *platelets* (3.13) are suspended

3.15
red blood cell additive solution
RAS
solution added to packed red cells to increase the storage life of red blood cells and prevent haemolysis

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3.16
platelet storage bag
PSB
bag suitable for appropriate storage of a therapeutic dose of platelet concentrates obtained from a single donation

3.17
red blood cell storage bag
bag suitable for storage of a therapeutic dose of red cells obtained from a single donation

3.18
pre-collection sampling device
device integrated in the collect line of blood collection systems or aphaeresis disposable sets designed to allow blood samples to be obtained at the beginning of a collection procedure without breaching the sterility of the collected components

Note 1 to entry: Usually incorporates a small reservoir from which the required blood samples are withdrawn. If a skin plug is obtained at the point of venepuncture, it is likely to be trapped in the reservoir rather than being drawn into the collected component(s), thereby, reducing the risk of bacterial contamination of the collected component(s).

Note 2 to entry: Also called PDS (pre-donation sampling device).

3.19
post-collection sampling device
device that can be integrated to allow a blood component sample to be taken, for example, for sterility testing or bacterial screening

3.20
needlestick protection device
NPD
device integrated in the donor line of blood bag systems containing the donor needle and designed to prevent undesirable needle sticks after use of the donor needle

Note 1 to entry: See ISO 23908.

3.21
replacement fluid
fluid used during an aphaeresis procedure to replace some or all of the blood volume associated with the collected components

3.22
anticoagulant safety connector
connector (3.4) specifically intended for use with *citrate anticoagulant* (3.5) to prevent accidental misconnection of anticoagulant with *replacement fluid* (3.21)

Note 1 to entry: An appropriate ISO standard is under preparation (ISO 18250-8).

3.23
shelf-life
period between the date of sterilization and the expiry date after which the sets should not be used

3.24
sterile barrier filter
filter intended to prevent micro-organisms or bacteria from entering a sterile *fluid pathway* (3.8)

4 Dimensions

Figure 1, Figure 2, Figure 3, and Figure 4 illustrate the components of an aphaeresis blood bag system with integrated features. The general drawings and the drawing of each feature are for guidance only.

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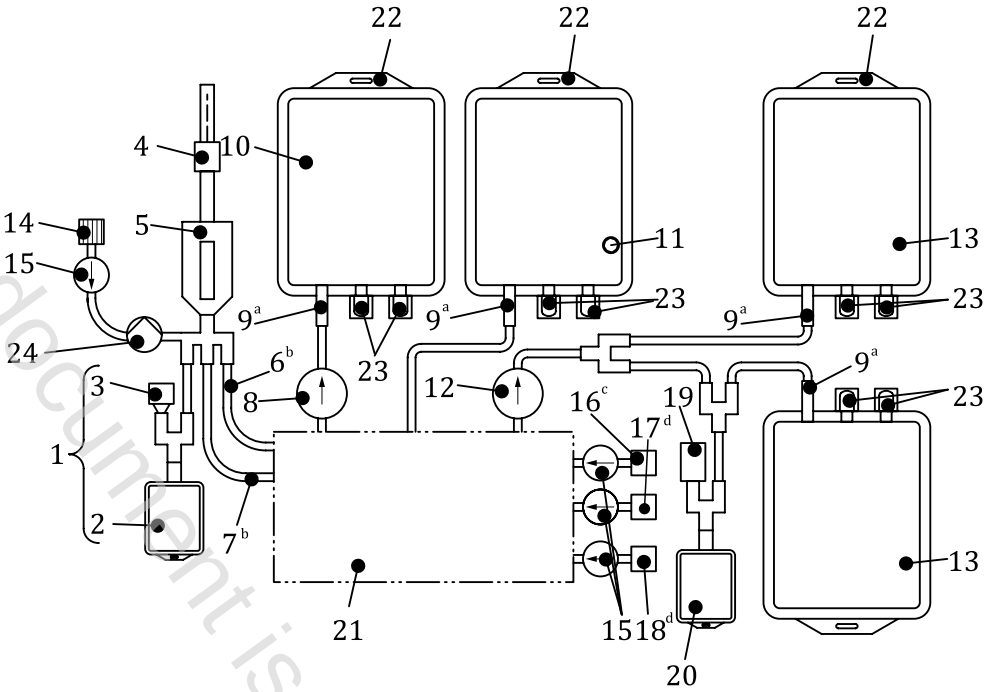

Key

1	pre-collection sampling device	15	sterile barrier filter
2	pre-collection sampling container	16	replacement fluid line if applicable to the set shall be provided with spike in accordance with ISO 8536-4 or a needle for fluid containers with narrow septums
3	multiple sampling device	17	red cell additive solution (RAS) connection to the extracorporeal circuit - male luer in accordance with ISO 594-2
4	access and return line needle (or connection device)	18	platelet additive solution (PAS) connection to the extracorporeal circuit - female luer in accordance with ISO 594-2
5	needle stick protection device (NPD)	19	bacterial sampling port
6	access line to aphaeresis extracorporeal circuit from donor or patient	20	post-collection sample container
7	return line from aphaeresis extracorporeal circuit to donor or patient	21	aphaeresis extracorporeal circuit (not covered by this part of ISO 3826)
8	leucocyte filter for red blood cells (LCF)	22	hanger eyelet
9	inlet port	23	outlet port
10	red blood cell storage bag	24	anticoagulant metering pump
11	plasma storage bag	a	Means of closure. The means can be positioned at other sites.
12	leucocyte filter for platelets (LCF)	b	The position of the lines can be different than depicted.
13	platelet storage bag (PSB)	c	Spike design is defined in ISO 8536-4.
14	anticoagulant safety connector for citrate anticoagulant	d	Additive (preservative) solution lines are optional and can be different than depicted.

Figure 1 — Schematic representation of components of a single needle donor aphaeresis blood bag system with integrated features — red cell blood bag with in-line leucocyte filter, platelet storage bag with in-line leucocyte filter, and pre-/post-donation sampling

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