RAVIMED

Blood Bags Short Description

v. 02/2021

COMPANY DESCRIPTION

RAVIMED Ltd., a manufacturer of medical devices and medicinal products, was created in 1991. It provides: sets of PVC bags for blood colletion, storage and preparation, medicinal products, individual anti-chemical protection sets, autoinjectors against Toxic Warfare Agents and laboratory services.
The highest quality of production is confirmed by ISO 9001, ISO 13845, CE, GMP, GLP, GDP certificates and many local, national registrations.

TÜV NORD

CERTIFICATE

Management system as per
PN-EN ISO 9001 : 2009

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it i

Zakład Produkcji Sprzętu Medyczn
RAVIMED Sp. z o.o.
ul. Polna 54, PL / 05-119 Łajski

applies a management system in line with the above standard fo

Design, manufacture, sterilization, qualit
of disposable medical devices for blood
Physicochemical, chemical and pharmac

Certificate Registration No. AC090 100/1327/4254/2015
Audit Report No. PL4245/2015

Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

This certification was conducted in accordance with the TÜV NOI
subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o. ul. Mickiewicza

TÜV NORD

CERTIFICATE

Management system as per
PN-EN ISO 13485:2012
Medical devices - Quality management systems - Requirements fo

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is here

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Design, manufacture, sterilization, quality co
of disposable medical devices for blood colle

Regardless of the fact that TÜV NORD Polska Sp. z o.o. is a notified body No.
a Certificate of Conformity within the meaning of Directive 93/42/EEC and is n

Certificate Registration No. TNP/MD/0163/4254/2015
Audit Report No. PL4245/2015

Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

This certification was conducted in accordance with the TÜV NORD Po
subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o. ul. Mickiewicza 29

TÜV NORD

CERTYFIKAT WE / EC CERTIFICATE

zgodny z 93/42/EWG Załącznik II(b.p. 4) / acc. 93/42/EEC Annex II(w.o. 4)

Niniejszym zaświadcza się, że firma / *This certifies, that the company*

Zakład Produkcji Sprzętu Medycznego
RAVIMED Sp. z o.o.
ul. Polna 54, PL / 05-119 Łajski

dla kategorii wyrobów sterylnych klasy IIb / *for the product category class IIb in sterile condition*
(Lista wyrobów patrz załącznik 1 / *List of products see annex 1*)

Zestaw pojemników do pobierania, przechowywania i preparatyki krwi.
Containers for blood collection, storage and preparation.

stosuje system zapewnienia jakości w projektowaniu, produkcji i kontroli końcowej wymienionych wyrobów zgodny z wymaganiami Załącznika II (z wyłączeniem sekcji 4) dyrektywy 93/42/EWG. Dodatkowo, przy znaku CE musi zostać naniesiony numer identyfikacyjny jednostki notyfikowanej. Ważność tego certyfikatu zależna jest od utrzymania systemu zapewnienia jakości zgodnego z wymaganiami dyrektywy i jego nadzorowania przez jednostkę notyfikowaną zgodnie z Załącznikiem II, rozdział 5. Certyfikat nie może być przenoszony pod żadnym warunkiem.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (excluding section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Nr rej. / *Reg.-No.* TNP/MDD/0164/4245/2015
Raport nr / Report No.: PL4245/2015

Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

TÜV NORD Polska Sp. z o.o.
ul. Mickiewicza 29 40-085 Katowice

☎ +48 32 786 46 46, Fax +48 32 786 46 01
www.tuv-nord.pl, biuro@tuv-nord.pl

Dopuszcza się kopiowania certyfikatu tylko w niezmienionej postaci. / *Copies of this certificate only without changes.*

RAVIMED's long-standing experience, and its modern scientific research laboratories, are the base for constant development and study of advanced and natural environmentally friendly products and medical technologies.
RAVIMED is in partnership with many institutes and university departments in both Poland and other European countries.
Numerous awards and honours testify to Ravimed's efficient collaboration.

PRODUCT DESCRIPTION

The RAVIMED blood bags are designed for safe and effective blood collection and its further processing and storage. The simplicity of servicing combined with the highest quality of performance facilitates efficient work and optimal use of blood components. An extremely sharp needle was designed with the patient's comfort in mind. A broad selection of container configurations enable adjusting thesets for all the needs of the modern Blood Service

Containers are made of PVC foil type Transfufol 3222, and containers for blood platelets storage of PVC foil type Transfufol 3224 (thickness: 0,35 mm) produced by Renolit BV.
Tubing have internal diameter of 3 mm and external diameter of 4,2 mm. Donor tubing's length is 110-150 cm, transfer bags connecting tubing have length 20-70cm depending on the set type.
The needle, 16 G size, is made of stainless steel with polypropylene cover.

Blood preservative solutions can contain citric acid, sodium citrate, sodium phosphate, glucose, adenine, sodium chloride and mannitol.
ACD stands for qualitative composition of the solution and is an abbreviation of first letters of its constituents - Acid citric, Citrate Sodium, Dextrose,
CPDA-1- Citrate, Phosphate, Dextrose, Adenine,
CPD - Citrate, Phosphate, Dextrose,
SAGM - Saline, Adenine, Glucose, Mannitol.
Blood preservative solutions provide anticoagulation of 450 ml of blood, its storage and full validity for:

CPD - 21 days
CPDA-1 - 35 days
SAGM - 42 days
ACD(A)and(B) - 21 days

Contents of the box depends on the type of Blood Collection Bags:

Type of product	Quantity in one box	Approx. net weight, kg	Number of sets in PP bag x number of PP bags in one box
450 CPDA-1	72	9,1	9 x 8
250/150 CPDA-1	64	7,7	8 x 8
350/300 CPDA-1	64	9,6	8 x 8
450/300 CPDA-1	64	11,9	8 x 8
450/400 CPDA-1	64	11,9	8 x 8
450/300/300 CPDA-1	48	10,4	8 x 6
450/300/300/300 CPD/SAGM	40	14,3	8 x 5
500/300//500/300 CPD	40	13,0	8 x 5
Cord blood set CPD	50	6,1	10 x 5
Placental blood set CPD	50	6,1	10 x 5
4% sodium citrate in 0,9% NaCl	60	18,2	without PP bags
ACD(A) 250 ml	60	17,6	without PP bags
ACD(A) 500 ml	20	11,6	2 x 10
Transfer 300 ml	100	4,5	10 x 10
Transfer 600 ml	100	5,8	10 x 10
Transfer 1000 ml	100	6,4	10 x 10
Transfer 150/150/150/150 ml	40	5,2	5 x 8
Sets with leukocyte reduction filter CPD/SAGM	24	9,9	3 x 8
Sets with leukocyte reduction filter CPDA-1	28	10,5	4 x 7
Washing kit	64	9,6	8 x 8

Packing of the product

The shelf life time of the sets of blood bags with anticoagulants is 36 months.
Blood Collection Bags are packed individually into PE bag.
Then into collective packing made of PP bag and eventually into boxes made of three-layer carton.
Into each box we put a copy of instruction for use and copy of Quality Control Certificate.
30 boxes are packed on one pallet in five layers.
Dimensions of boxes are: 36cm x 36cm x 32cm (height)

SINGLE

Type of Blood Collection Bag	Capacity ml	Type of Anticoagulant	Code name
Single	250	CPDA-1	RS250Ca
	350		RS350Ca
	450		RS450Ca

DOUBLE

Type of Blood Collection Bag	Capacity ml	Type of Anticoagulant	Code name
Double	250/150	CPDA-1	RD250/150Ca
	350/300		RD350/300Ca
	450/300		RD450/300Ca
	450/400		RD450/400Ca
	500/400		RD500/400Ca

TRIPLE

Type of Blood Collection Bag	Capacity ml	Type of Anticoagulant	Code name
Triple	250/150/150	CPDA-1	RT250/150/150Ca
	350/150/150		RT350/150/150Ca
	450/150/150		RT450/150/150Ca
	350/300/300		RT350/300/300Ca
	450/300/300		RT450/300/300Ca
	500/300/300		RT500/300/300Ca
Triple for platelets storage	450/300/300		RT450/300/300CaP
Triple	450/300/150		RT450/300/150Ca
Triple	450/300/300	CPD-SAGM	RT450/300/300CSm
	450/400/300		RT450/400/300CSm
	450/300/400		RT450/300/400CSm
Triple for platelets storage	450/300/300		RT450/300/300CSmP
	450/400/300		RT450/400/300CSmP
Triple	450/400/400		RT450/400/400CSm
Triple for platelets storage	450/400/400	CPD-SAGM	RT450/400/400CSmP
		CPDA-1	RT450/400/400CaP

TRIPLE

СТРОЕННЫЙ КОНТЕЙНЕР
ДЛЯ ЗАГОТОВКИ
450 мл КРОВИ
600 ml
CPD
63 ml
450 ml
MD
XXXX-XX
RT450/400/400CSm
XXXXXX
400 ml
SAGM
150 ml
RT450/400/400CSm

QUADRUPLE

Type of Blood Collection Bag	Capacity ml	Type of Anticoagulant	Code name
Quadruple	450/3x300	CPDA-1	RQ450/300/300/300Ca
Quadruple for platelets storage	450/3x300		RQ450/300/300/300CaP
Quadruple	450/300/300/300	CPD-SAGM	RQ450/300/300/300CSm
	450/400/300/300		RQ450/400/300/300CSm
	450/400/400/400		RQ450/400/400/400CSm
	450/300/150/300		RQ450/300/150/300CSm
	450/400/150/300		RQ450/400/150/300CSm
Quadruple for platelets storage	450/300/300/300		RQ450/300/300/300CSmP
	450/400/300/300		RQ450/400/300/300CSmP
	450/400/400/400		RQ450/400/400/400CSmP
	450/300/150/300		RQ450/300/150/300CSmP
	450/400/150/300		RQ450/400/150/300CSmP
	450/400/400/400		RQ450/400/2x400CSmP

QUADRUPLE

Double Plasmapheresis

Type of Blood Collection Bag	Capacity ml	Type of Anticoagulant	Code name
Double Plasmapheresis	450/300//450/300	CPD or 4% Sodium Citrate, (dihydrous)	R2P450/300/450/300C
	500/300//500/300		R2P500/300/500/300C
	500/300//500/300		R2P500/400/500/400C

Cord Blood Collection Set

Transfer bags

Type of Blood Collection Bag	Capacity ml	Code name
Transfer	100	RTr100
	150	RTr150
	250	RTr250
	300	RTr300
	350	RTr350
	450	RTr450
	500	RTr500
	600	RTr600
	1000	RTr1000
Transfer for platelets storage	600	RTr600P
	1000	RTr1000P

Sets with leukocyte reduction filter WBF

Type of Blood Collection Bag	Capacity ml	Type of Anticoagulant	Code name
Quadruple	450/450/2x300	CPD/SAGM	RQ450/450/300/300CSmL
	450/400/2x300		RQ450/400/300/300CSmL
	450/400/2x400		RQ450/400/400/400CSmL
Triple	450/450/300	CPDA-1	RT450/450/300CaL

Sets with leukocyte reduction filter RBC

quadruple and quintuple

ANTICOAGULANTS

Type of Blood Collection Bag	Capacity ml	Type of Anticoagulant	Code name
Anticoagulant	250	4% Sodium Citrate in 0,9% Sodium Chloride	RS250Scs
	500		RS500Scs
	250	ACD(A)	RS250A
	500		RS500A

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