MEAPLASMA

Universal Regenerative complex MeaPlasma.

- Overview.
- Equipment.
- Application.

MEAPLASMA

What is MeaPlasma?

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This is a regenerative complex, based on the development, built on the previous experience of our colleagues - doctors who tried to revive the method of treatment and rejuvenation of a patient known by the end of the 19th century with its own blood - autohemo-, and later - autoplasmotherapy.

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How we created MeaPlasma?

Platelet rich plasma is far from being an innovation in medicine and cosmetology: the history of the use of human plasma itself has several decades. For a long time it has been proven effective, accumulated experience and created many techniques for its use, but ...
Their Achilles' heel has always been equipment – cumbersome and expensive: for the preparation of the drug, entire laboratories were required before. This significantly limited the possibility of using autoplasma. Only large clinics with separate rooms, considerable funds for the purchase of everything needed and a staff of specially trained personnel could fully use this method.
Many manufacturers have tried to solve the problem of the high cost and laboriousness of obtaining blood components. In an effort to reduce the cost of production of equipment and supplies, the developers sacrificed the main thing – the quality of the final product. As a result, the very idea of creating economical models of equipment, and the results of treatment with autoplasma, which lost its unique reparative properties, due to violations of technology, also depreciated.
We, practicing physicians, spent five years studying the mistakes of previous manufacturers, found out the reasons for their failures, developed and started the production of a full line of equipment for the preparation of autologous plasma. – MeaPlasma is a modern technology that includes centrifuges, dry baths and consumables required for the treatment with the autologous plasma.

They favorably differ from their predecessors because of:

- Compact size of equipment
- Convenience and ease of use
- Reliability and complete safety
- Competitive cost of both devices and consumables

And all this – without prejudice to the quality of the finished autologous plasma: under the new conditions it retains the ability to restore, in the shortest possible time, the affected mucous membranes, muscle, bone and ligament tissues.

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The line of equipment for all fields of application of autologous plasma in treatment was the result of many years of research of the application of this technology in medical practice all over the world. In addition, all MEAPLASMA products are created by doctors for doctors, considering the mistakes made by other manufacturers earlier.

The goal of creating of the line of equipment MeaPlasma was to optimize and simplify the use of methods of autologous plasma therapy by a practicing physician. During production, we focused on world quality standards, giving the product the maximum efficiency and safety of its application in medical practice.

One of our goals was to ensure maximum availability of this technique without reducing the quality of the technology.

Our team was able to make a premium product affordable for a wide range of patients.

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MeaPlasma is the newest line of vacuum tubes and equipment for PRGF procedures and autologous plasma therapy.

MeaPlasma tubes meet the highest quality standards.

For production we use only the best components:

- Borosilicate glass of medical purpose.
- Low molecular weight heparin FDA / USP-quality for In-Vivo application.
- Membrane gel, resistant to sterilization by gamma rays.

All MeaPlasma tubes are 100% sterile and safe to use.

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Why do we so loudly call our product – an innovation, a breakthrough and even a revolution in medicine?
Because we managed to solve many tasks at once and created an extraordinary instrument for treatment and rejuvenation with following advantages.

- **Efficiency**
- **Safety**
- **Rational and cost-effective treatment**
- **Accessible for the patients**

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History of autologous plasma therapy.

As an effective method of treatment, autologous plasma therapy started with the use of whole blood for intramuscular and subcutaneous injections in the beginning of the last century. The first laboratory experiments with human blood were put by prominent scientists August Bir and Andreas Leven, but the precedence, of course, belongs to the great Russian surgeon V.F. Voino-Yasenetsky.

The beginning of the 20th century was marked by the Russian-Japanese war. Thousands of soldiers died from wounds: sepsis, severe injuries to limbs and internal organs, in the absence of antibiotics at that time left too little chance of survival.

Suffered and civilians too: furunculosis, bacterial infections of the respiratory tract, purulent wounds often ended tragically precisely because of the complete medicine helplessness and doctors around the world.

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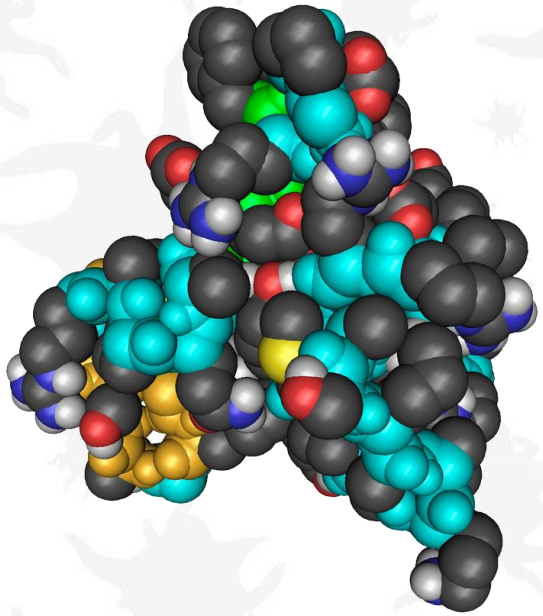
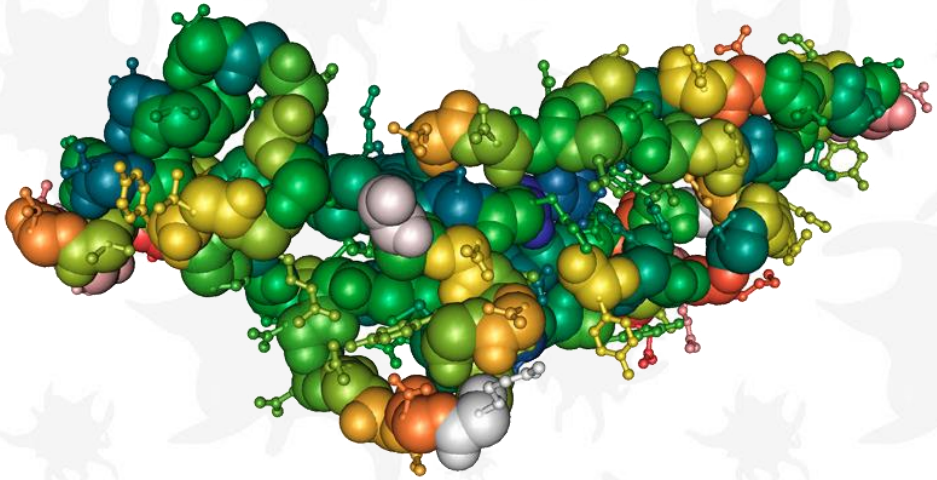
Факторы роста

Growth factors are what speeds up wound healing, promotes blood rejuvenation, restores hair growth in baldness.

They accumulate in the alpha-granules of platelets.

With bleeding or the appearance of an abscess, platelets are activated simultaneously with the release of alpha-granules and the activation of growth factors. In the first 10 minutes after the fibrin clot formation, approximately 70 percent of the growth factors are released from the platelets. The remaining factors are secreted for another hour. In the next 8 days, an additional number of growth factors are synthesized, after which the platelets die off.





Autologous plasma accumulate various factors: in a saturated preparation their content increases several times, which multiplies the regenerative properties of platelets many times.

Here are the types of growth factors found:

- insulin-like growth factor (IGF-I, IGF-II)
- platelet growth factor (PDGF)
- epidermal growth factor (EGF)
- fibroblast growth factor (FGF)
- vascular endothelial growth factor (VEGF)
- placental growth factors (PLGF-1/2)

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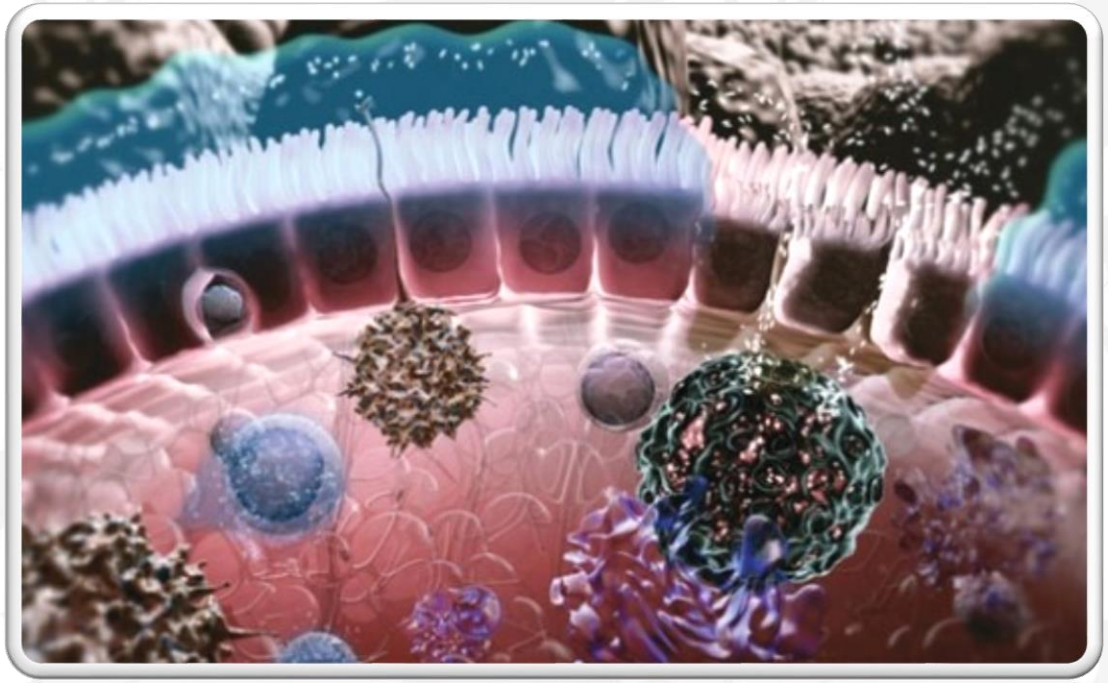
What are the functions of growth factors?

First of all, tissue regeneration is provided by two kinds of factors - epidermal and platelet.

Cellular growth, the formation of bone tissue - this is their main merit.

Insulin-like factor strengthens and synthesizes connective tissue, and stimulates cell growth.



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MeaPlasma research is conducted on the basis State Medical Academy of the Nizhny Novgorod and under the leadership of Claudia Nikolaevna Kontorschikova.

Claudia Nikolaevna Kontorschikova

Professor, Head of the Department of Clinical Laboratory Diagnostics of Nizhny Novgorod State Medical Academy.

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To justify the effectiveness of the MeaPlasma equipment, a unique laboratory analysis was performed.

The case of study was to calculate the quantity of platelet growth factors in the obtained autologous platelet plasma.

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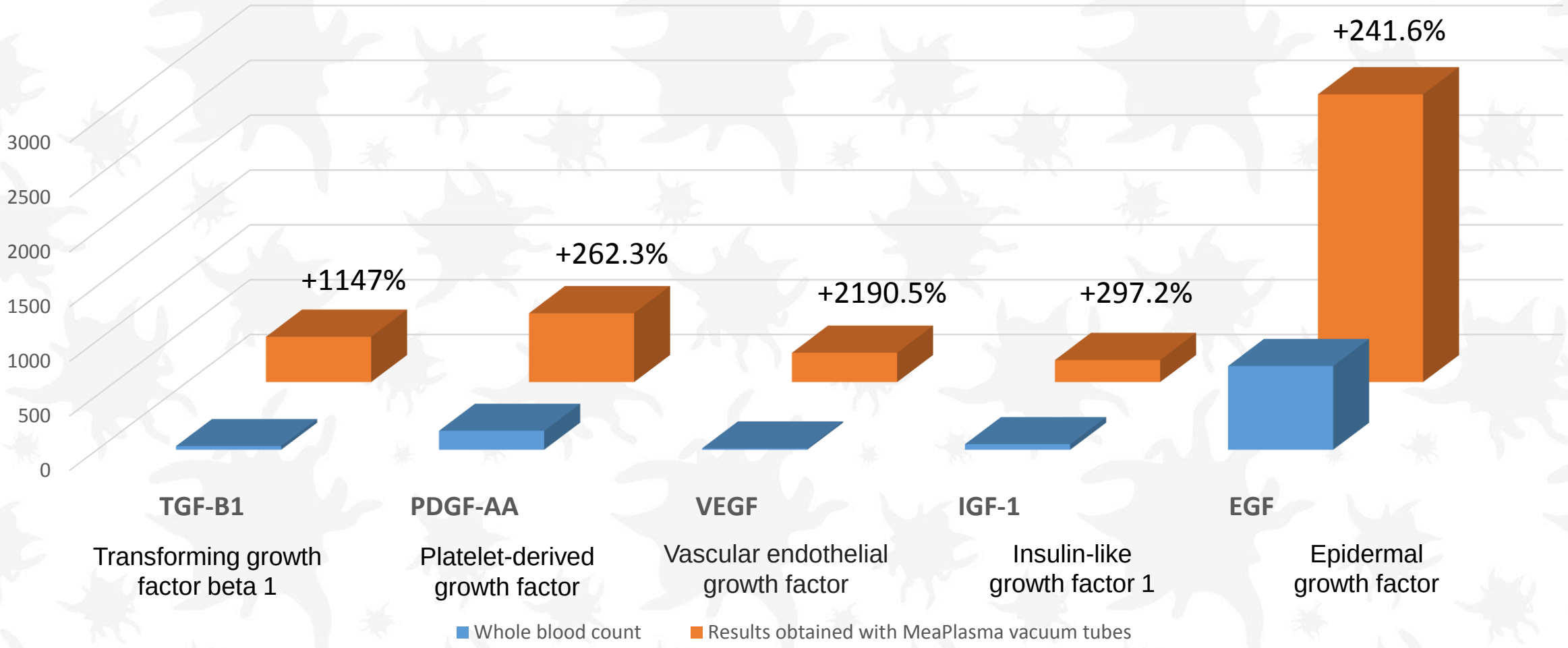
Diagram of growth factors in blood plasma on MeaPlasma equipment



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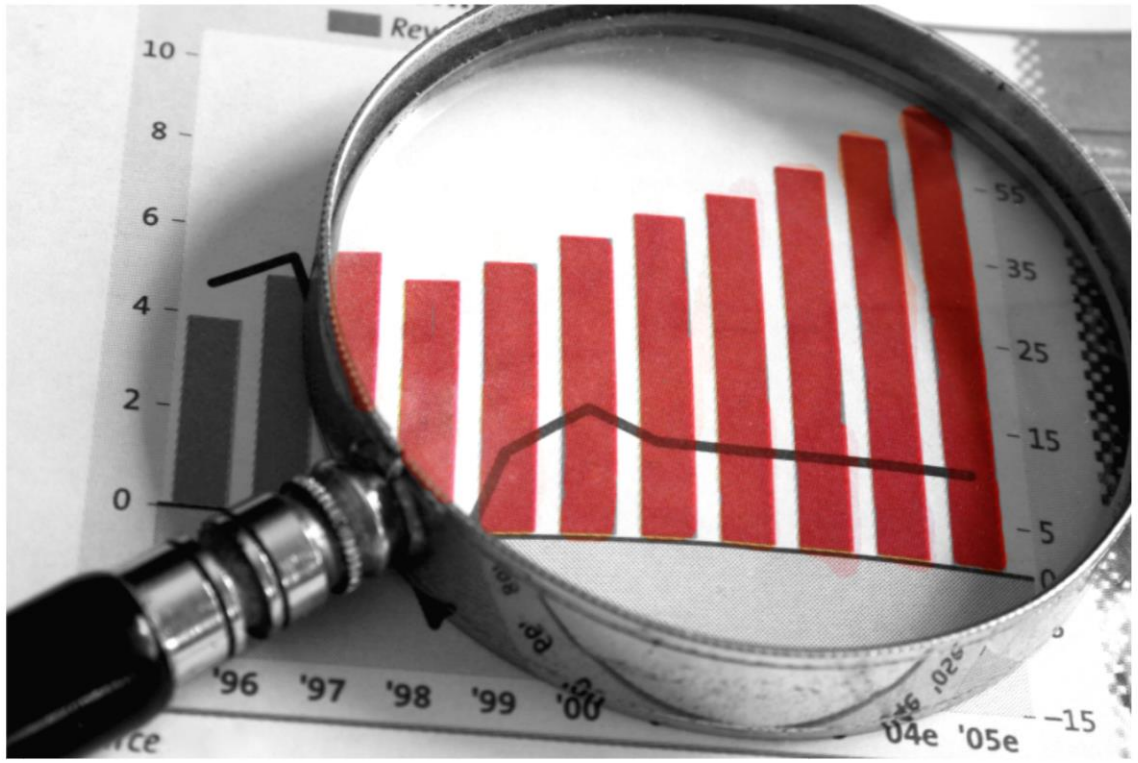
The result:

The platelet plasma obtained by the new method using the MeaPlasma equipment is effective due to the accumulation of the most important platelet growth factors for tissues regeneration.



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Attention! "Can these growth factors cause cancer or neoplasms?» -
the common question from practicing doctors.

Absolutely responsibly declare: the growth of malignant neoplasms in the treatment of platelet autoplasma is completely excluded. It is important to know that growth factors are natural proteins, they are not mutagens, and therefore can not cause any malignant changes in the structure of cells. Patients are absolutely safe!

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Here are the main properties of autologous plasma:

- Starts the process of building healthy epithelial, muscle, connective tissues.
- The high content of all kinds of growth factors – primary, secondary and tertiary, which are combined naturally in contrast to many artificially created drugs.
- Simultaneous influence on all stages of regeneration: it supplies both "bricks" and "builders“.
- Ensuring the synergy of all the recovery processes in the body.

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Clinical effects

There are a lot of them, and they are not only well expressed, but, most importantly, have prolonged action:

- Tissues recover due to the action of growth factors.
- Essential improvement of metabolic processes in the skin.
- Activation of local immunity.
- Renewal of normal microcirculation of blood, tissue respiration.

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How to obtain autologous plasma.

To obtain a preparation of platelet mass, three components are needed: a portion of the patient's blood, a special vacuum tube and a centrifuge with certain settings.

Using a regular syringe draw a small quantity (20-25ml) of venous blood and place it in the vacuum tube before it starts to coagulate.

Single stage centrifugation is enough: in a short time, red blood cells, leukocytes and other formed blood elements are separated from the plasma. Formed blood elements remain at the bottom of the MeaPlasma tube, and plasma and platelets are on top.

As you can see, everything is extremely simple: you just need to take the blood and move it into a MeaPlasma tube.

The equipment will do the rest itself in a very short time - not more than 20 minutes.

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Most often we are asked:

- What is the difference between the vacuum tubes?
- Why I should use exactly your MeaPlasma tube?

If to answer very briefly, then - the whole thing is about patient's safety.

Safety implies quality of raw materials:

- The tube is made of special type of medical grade glass.
- Additive – Thixotropic Separation Gel.
- Finely dispersed on the walls of tube sodium heparin of IN-VIVO quality.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 16 01 42464 028

Manufacturer: Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): Disposable Vacuum Blood Collection System, Disposable Umbilical Cord Scissors

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report No.: SH1611117

Valid from: 2016-02-29
Valid until: 2018-06-08

Date, 2016-02-26

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

CERTIFICATE

No. Q1N 16 01 42464 026

Holder of Certificate: Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Design and Development, Production and Distribution of Plastic Centrifuge Tubes, Plastic Pipette Tips, Plastic Culture Dishes, Plastic Forceps, Plastic Test Tubes, Plastic Sample Cups, Plastic First Aid Cases and Disposable Vacuum Blood Tubes, Disposable Vacuum Blood Collection Systems, Disposable Vaginal Speculum, Disposable Sterile Swabs, Transportation Swabs with Medium, Micro Blood Collection Tubes, Capillary Blood Collection Tubes, Vacuum Urine Collection Sets, Disposable Umbilical Cord Scissors Disposable Specimen Container, Needle Holder, Disposable Non Vacuum Blood tubes, Disposable Anoscope, Disposable Loop Stick, Sterile Vaginal Applicator

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1611117

Valid from: 2016-02-29
Valid until: 2019-02-28

Date, 2016-02-26

Stefan Preiß

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DAkkS

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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MeaPlasma tubes are manufactured in accordance with the GMP (Good Manufacturing Practice) standard, which is known for its stringent requirements for the entire production cycle, from the quality of the glass to the packaging.

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Enoray

CERTIFICATE OF ANALYSIS

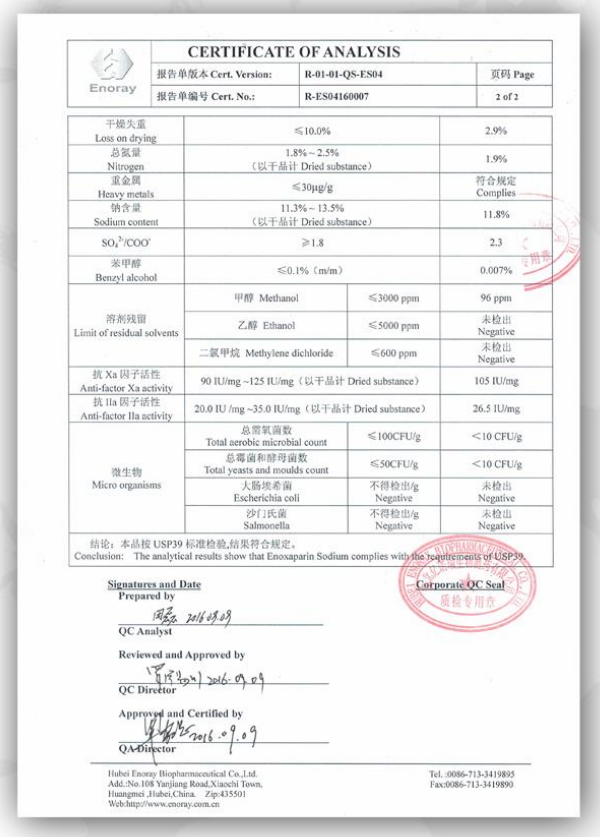
报告单版本 Cert. Version:	R-01-01-QS-ES04	页码 Page
报告单编号 Cert. No.:	R-ES04160007	1 of 2

品　名 Product Name	依诺肝素钠 Enoxaparin Sodium	标准代号 Specification Code	QS-ES04-01
批　号 Batch/Lot No.	ES03160801	批分析档案号 No. of Analysis	A-ES04160007
数　量 Quantity	30.606 Kg	有效期至 Expiry Period	2019.07
生产日期 Mfg. Date	2016.08.13	报告日期 Report Date	2016.09.09

检验项目 Testing items	标准 Specification	检验结果 Test result
性状 Characters	白色或类白色粉末，有引湿性。 A white or almost white powder, hygroscopic.	符合规定 Complies
1,6-脱水结构 1,6-anhydro derivative	15%~25%	19%
鉴别 Identification	A: 在 231±2nm 处有最大光吸收。 The spectra exhibit maxima at 231±2nm.	符合规定 Complies
	B: ^{13}C 核磁共振图谱。 ^{13}C -NMR spectrum.	符合规定 Complies
	C: 抗 Xa 因子/抗 IIa 因子比率 3.3~5.3 Anti-FXa/Anti-FIIa 3.3 to 5.3	4.0
	D: 重均分子量在 3800 和 5000 之间 The weight-average molecular weight is 4500 daltons, the range being between 3800 and 5000 Da.	4743
	分子量小于 2000 的比率：12.0%~20.0% The percent has a molecular weight of less than 2000 Da, the range being between 12.0% and 20.0 %.	15.2%
	分子量位于 2000 和 8000 之间的比率为：68.0%~82.0% The percent has a molecular weight between 2000 and 8000 Da, the range being between 68.0% and 82.0%.	71.2%
	分子量大于 8000 的比率：≤18.0% The percent has a molecular weight of more than 8000 Da, the range being not more than 18.0 %.	13.7%
	E:水溶液显钠盐的鉴别反应。 It responds to the test for Sodium.	符合规定 Complies
光吸收 Specific absorbance	在 231±2nm 比吸光系数在 14.0~20.0 之间（干品） The specific absorbance at the maximum absorbance at 231±2 nm and the specific absorbance between 14.0 and 20.0(dried substance)	16.6
细菌内毒素 Bacterial endotoxins	<0.01 USP EU/Anti-FXa IU activity	符合规定 Complies
10%溶液酸碱度 10% concentration pH	6.2~7.7	7.1

Hubei Enoray Biopharmaceutical Co.,Ltd.
Add.:No.108 Yanjiang Road,Xiaochi Town,
Huangmei ,Hubei,China. Zip:435501
Web:http://www.enoray.com.cn

Tel. :0086-713-3419895
Fax:0086-713-3419890



Enoray

CERTIFICATE OF ANALYSIS

报告单版本 Cert. Version:	R-01-01-QS-ES04	页码 Page
报告单编号 Cert. No.:	R-ES04160007	2 of 2

干燥失重 Loss on drying	≤10.0%		2.9%
总氮量 Nitrogen	1.8%～2.5% （以干品计 Dried substance）		1.9%
重金属 Heavy metals	≤30μg/g		符合规定 Complies
钠含量 Sodium content	11.3%～13.5% （以干品计 Dried substance）		11.8%
SO_4^{2-}/COO^-	≥1.8		2.3
苯甲醇 Benzyl alcohol	≤0.1%（m/m）		0.007%
溶剂残留 Limit of residual solvents	甲醇 Methanol	≤3000 ppm	96 ppm
	乙醇 Ethanol	≤5000 ppm	未检出 Negative
	二氯甲烷 Methylene dichloride	≤600 ppm	未检出 Negative
抗 Xa 因子活性 Anti-factor Xa activity	90 IU/mg ~125 IU/mg（以干品计 Dried substance）		105 IU/mg
抗 IIa 因子活性 Anti-factor IIa activity	20.0 IU /mg ~35.0 IU/mg（以干品计 Dried substance）		26.5 IU/mg
微生物 Micro organisms	总需氧菌数 Total aerobic microbial count	≤100CFU/g	<10 CFU/g
	总霉菌和酵母菌数 Total yeasts and moulds count	≤50CFU/g	<10 CFU/g
	大肠埃希菌 Escherichia coli	不得检出/g Negative	未检出 Negative
	沙门氏菌 Salmonella	不得检出/g Negative	未检出 Negative

结论：本品按 USP39 标准检验,结果符合规定。
Conclusion: The analytical results show that Enoxaparin Sodium complies with the requirements of USP39.

Signatures and Date
Prepared by
2016.09.09
QC Analyst

Reviewed and Approved by
2016.09.09
QC Director

Approved and Certified by
2016.09.09
QA Director

Corporate QC Seal

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Huangmei ,Hubei,China. Zip:435501
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Tel. :0086-713-3419895
Fax:0086-713-3419890

Sodium Heparin (anticoagulant)

In production, Meaplasma uses only high-quality components.

Sodium Heparin sprayed on the Meaplasma tube wall meets USP / FDA standards and has an average molecular mass of ~ 4700 Dalton.

This allows the use of obtained plasma for injection into tissues without any risk to the patient.

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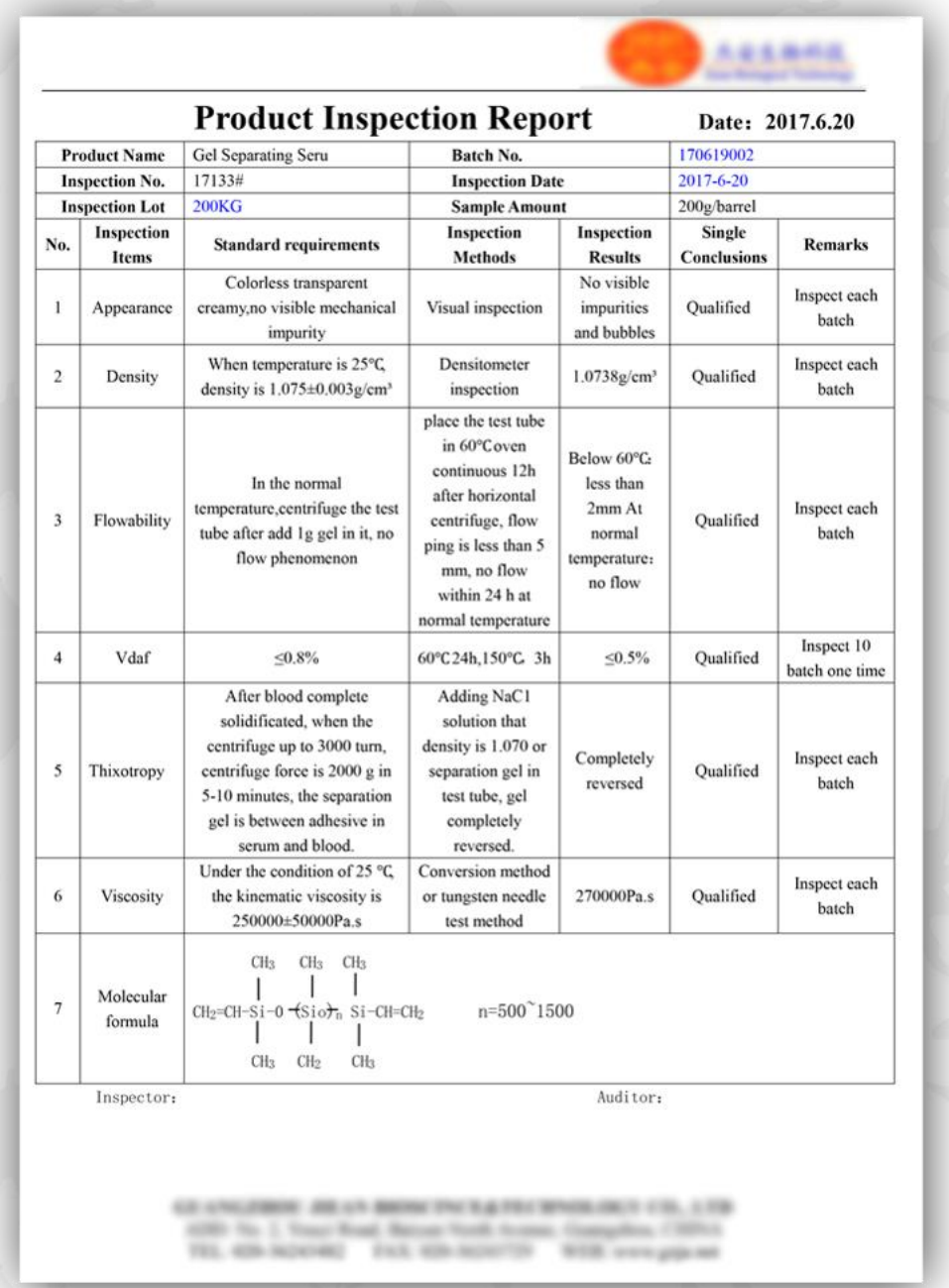
Thixotropic separation gel.

High-quality thixotropic gel, produced specifically for the Meaplasma technique.

The gel keeps the erythrocytes and leukocytes separated and reliably isolated from the platelet plasma.

Each batch of gel passes all necessary technical tests and is supported by all necessary documents and certificates.



Product Inspection Report

Date: 2017.6.20

Product Name	Gel Separating Seru	Batch No.	170619002
Inspection No.	17133#	Inspection Date	2017-6-20
Inspection Lot	200KG	Sample Amount	200g/barrel

No.	Inspection Items	Standard requirements	Inspection Methods	Inspection Results	Single Conclusions	Remarks
1	Appearance	Colorless transparent creamy,no visible mechanical impurity	Visual inspection	No visible impurities and bubbles	Qualified	Inspect each batch
2	Density	When temperature is 25℃, density is 1.075±0.003g/cm³	Densitometer inspection	1.0738g/cm³	Qualified	Inspect each batch
3	Flowability	In the normal temperature,centrifuge the test tube after add 1g gel in it, no flow phenomenon	place the test tube in 60℃oven continuous 12h after horizontal centrifuge, flow ping is less than 5 mm, no flow within 24 h at normal temperature	Below 60℃: less than 2mm At normal temperature: no flow	Qualified	Inspect each batch
4	Vdaf	≤0.8%	60℃24h,150℃ 3h	≤0.5%	Qualified	Inspect 10 batch one time
5	Thixotropy	After blood complete solidificated, when the centrifuge up to 3000 turn, centrifuge force is 2000 g in 5-10 minutes, the separation gel is between adhesive in serum and blood.	Adding NaC1 solution that density is 1.070 or separation gel in test tube, gel completely reversed.	Completely reversed	Qualified	Inspect each batch
6	Viscosity	Under the condition of 25 ℃, the kinematic viscosity is 250000±50000Pa.s	Conversion method or tungsten needle test method	270000Pa.s	Qualified	Inspect each batch
7	Molecular formula	$CH_2{=}CH{-}Si(CH_3)_2{-}O{-}(Si(CH_3)_2{-}O)_n{-}Si(CH_3)_2{-}CH{=}CH_2$ n=500~1500				

Inspector: Auditor:

MEAPLASMA

Attention!

The use of non-certified test tubes may cause harm to the health of patients, since no one is responsible for the final result - the quality of the preparation obtained in such test tubes and the effect of treating them.

MEAPLASMA

What exactly ensures the quality of our tubes?

Glass – The tubes are made of borosilicate glass, which is very high hard and able to withstand the significant load many times.

This is an incomparably more profitable acquisition than other types of test tubes.

Gel – is a biopolymer thixotropic substance that, when centrifuged, becomes liquid and at the same time flawlessly filters the blood, dividing it into an erythrocyte clot and plasma.

Such filtering provides:

- High quality of absorption
- The necessary concentration of platelets in the future preparation
- Separation of plasma from leukocytes – the culprits of autoimmune reactions of the body, as well as from high molecular lipids.

MEAPLASMA

MeaPlasma is a full-cycle company.

We supply all necessary equipment* and consumables for the procedure.

The MeaPlasma kit includes:

- 1 test tube MeaPlasma
- 1 needle 22G
- 1 tube holder with adapter Luer-lock

*Centrifuges and Dry bath are sold separately.

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Centrifuge Basic

- Range: 300 ~ 4000 rpm (increment: 100rpm)
- Rotor diameter: 130 mm
- Max. RCF 2325xg
- Rotational accuracy: ± 10% rpm
- Number of tubes: 12 * 10 ml
- Timer: 0 to 99 minutes
- Protection: stop when opening the lid, overspeed, self-diagnosis.
- Noise level at 4000 rpm –≤75dB
- Touch control, display.
- Input voltage: AC 220V ± 22V 50Hz ± 1Hz
- Size: 350 × 350 × 325 mm

MEAPLASMA

MeaPlasma Premium Centrifuge

- Range: 300 ~ 4500 rpm (increment: 100rpm)
- Rotor diameter: 110 mm
- Max. RCF 2490xg (increment: 100xg)
- Rotational accuracy: ± 20rpm
- Number of test tubes: 16 * 10 ml
- Timer: 30 seconds to 99 minutes
- Protection: auto-blocking the lid, exceeding the speed, self-diagnosis.
- Noise level at 4500 rpm -≤56dB
- Touch control, display.
- Input voltage: AC100 ~ 230V, 50 / 60Hz
- Size: 300 x 431 x 178mm

MEAPLASMA

Dry Bath Mini-100

- Temperature range: from room temperature to 100 ° C
- Accuracy at 100 ° C: ≤ ± 0.5 ° C
- Temperature deviation of the heating unit at 40 ° C = 0.3 ° C
- Display accuracy: 0.1 ° C
- Timer: 0-999 min
- Maximum temperature: 100 ° C
- Touch control, display.
- Max. Power - 60W
- Size: (WxDxH) 150x100x100 mm

MEAPLASMA

Areas of application of MeaPlasma technology.

Cosmetology

Dentistry

Orthopedics and Traumatology

Trichology

Gynecology

Urology

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Safety and 100% effect of the obtained autologous plasma preparation can be achieved only if certain essential conditions are met:

- Use only the "right" tubes and equipment
- Strict compliance with the centrifugation protocol
- Complete absence of foreign substances in the plasma

Thank you!

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