FARMKOM PRODUCTION ASSOCIATION
LIMITED LIABILITY COMPANY (LLC PO FARMKOM)

Code according to All-Russian classifier of products by type of economic activity 2 14.19.32.120
The Russian Classification for Standards 11.140

APPROVED BY
the Director of LLC PO FARMKOM
_____/ E.V. Melnikova
"___"_____2019

DISPOSABLE MEDICAL PRODUCTS OF FLASHSPUN FABRIC

TS 14.19.32-001-19152126-2019
(first introduced)

Introduction date – "___" _____ 2019

DESIGNED BY
LLC PO FARMKOM

2019

Table of Content

1 PURPOSE AND SCOPE (INTRODUCTORY CLAUSE)

This technical specification was developed in accordance with GOST R 1.3 (hereinafter referred to as “TS”) and is applicable to Disposable Medical Products of flashspun fabric (hereinafter referred to as “Products”, “Scrub hats”, “Masks”), designed for compliance with sanitary-epidemiologic and hygienic requirements at medical and preventive treatment facilities.

Scope of application: during medical practice, at medical and preventive treatment facilities.

Design styles: disposable scrub hat of “Charlotte” style, protective medical mask.

Product coloring variants: pink, white, green, blue, black, orange.

Disposable, non-sterile products.

Potential users: medical staff, patients of medical and preventive treatment facilities.

Category depending of application potential risk – 1 under GOST 31508.

Climatic category: NF 4.2 under GOST 15150.

Recommended indications: compliance with sanitary-epidemiologic and hygienic requirements at medical and preventive treatment facilities.

Contraindication: mask material idiosyncrasy.

Adverse effects: no

Reparability: disposable, unrepairable product.

Category depending on possible failure consequences – B under GOST R 50444.

Product designation example when ordering:

“Scrub hat “Charlotte”, white color TS 14.19.32-01-19152126-2019

The list of documents referred to in the Technical Specifications is provided in Annex A.

2 PRODUCTS CONSUMER PROPERTIES (TECHNICAL REQUIREMENTS)

2.1 General Requirements

2.1.1 The product should comply with the requirements of GOST R 50444, this technical specification and be manufactured in accordance with the technological regulations approved by the company.

2.2 Basic Parameters and Characteristics

2.2.1 The basic technical characteristics for the medical product "Mask" should meet the requirements provided in the table 1.

Table 1

Name	Layers number	Fixation Type	Antibacterial Layer	Nose Clamp	Dimensions (mm) LxW
Protection Medical Mask	3	Shirring	Melt-blown	available	175x95

2.2.2 The effectiveness of bacterial filtration should be at least 95 %.

2.2.3 Specific pressure (air permeability) should be no more than 3 mmAq/cm^2.

2.2.4 The product design should be of 3 layers:

- 1st layer - spunbond (hydrophobic), weight 22 g/m²;
- 2nd layer – melt-blown - antibacterial filter, weight 20 g/m²;
- 3rd layer - spunbond (hydrophilic), weight 27 g/m².

2.2.5 Protective mask should be of shape with three folds**.** The width of each fold should be 15 mm.

2.2.6 The pressure drop between the outer and inner surfaces during the inhale or exhale should be less than 2 mmAq/cm^2.

2.2.7 Nose clamp should be at the top of the mask, the size is 70 mm; the clamp should be sewn in.

2.2.8 The static length of the shirring should be 16 cm and stretched length - 35 cm.

2.2.9 Splash resistance should be at least 120 mmHg.

2.2.10 Seams should be of welded type

2.2.11 The seam width should be 0.5-0.7 cm.

2.2.12 The edges should be sewn turndown with a closed cut of 0.3-0.4 cm wide in finished form, the value of the internal hem is 0.3 cm.

2.2.13 The shirring should be round of 1.8 mm diameter length, 16.5±1 cm length.

2.2.14 The basic parameters and technical characteristics for the medical product "Scrub hat" should meet the requirements provided in the table 2.

Table 2

Name	Layers Number	Fixation Type	Dimensions (mm) diameter
Charlotte scrub hat	1	Shirring	53 cm

2.2.15 The scrub hat should be antistatic.

2.2.16 Air permeability of "Scrub hat" should be at least 210 dm^3/cm^2*sec.

2.2.17 "Scrub hat" should be manufactured of hypoallergenic materials.

2.2.18 A two-row elastic band with a width of at least 4 mm should be welded around the "Scrub hat".

2.2.19 Seams should be manufactured with welded technology.

2.2.20 The width of the seam should be 0.5-0.7 cm.

2.2.21 The edges should be sewn turndown with a closed cut of 0.3-0.4 cm wide in finished form, the value of the internal hem is 0.3 cm.

2.2.22 The shirring should be round of 1.8 mm diameter length, 23±1 cm length.

2.3 **Materials Requirements**

2.3.1 Materials and purchased products meeting the requirements of the appropriate regulatory and (or) technical documents approved in the provided manner should be used that for the manufacture of products.

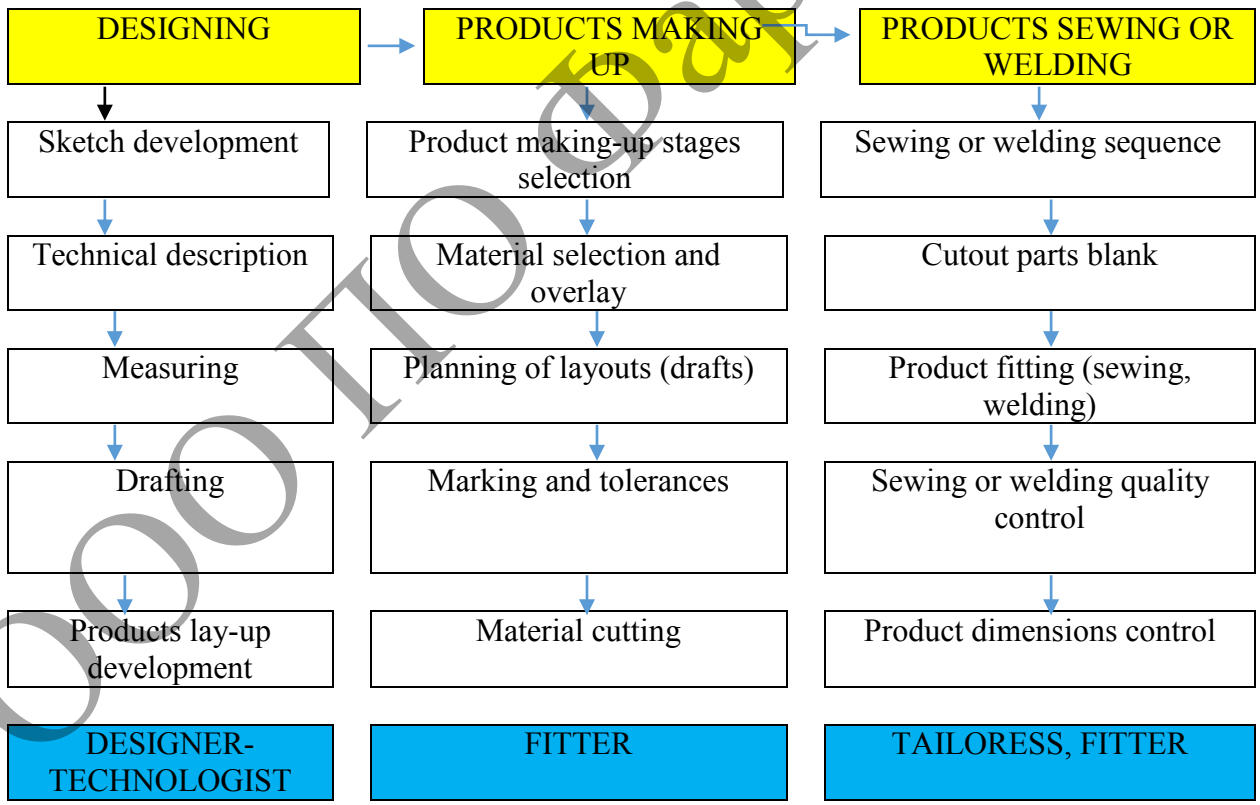
2.3.2 All materials used during the product manufacture, installation and operation should be environmentally friendly and should not have any harmful effect on humans and the environment under operating conditions.

2.3.3 Purchased products for their manufacture, including products of foreign manufacture, should have certificates of conformity or other documents confirming their quality and safety.

2.3.4 Materials used during the products manufacture:

- PP white dye concentrate 63776-M1-300;
- PP blue dye concentrate 63397-D2-300;
- Remafin Green PP green dye concentrate 63076203-ZT;
- PP black Basco PV concentrate 1910/12;
- Remafin Orange PP orange dye superconcentrate 23075752;
- SIBEX PP H270 FF/3 brand polypropylene - scrub hat, mask material;
- polyester is the shirring outer layer;
- polyurethane is the shimmer filler.

2.4 **Information about Medical Product Designing and Manufacture**



2.5 **Scope of Supply**

2.5.1 Scope of supply should comply with the table 3.

Table 3

Name	Quantity
Product	
Label	1 pc.
Application Instruction	1 pc.
Packing	

3 SAFETY REQUIREMENTS

3.1 Products should meet the requirements of sanitary-chemical and toxicological safety in accordance with GOST R 52770 and biological safety in accordance with GOST ISO 10993-1.

4 ENVIRONMENTAL PROTECTION REQUIREMENTS

4.1 The products are non-toxic and do not emit harmful substances into the environment during manufacture, testing, storage, transportation, operation.

4.2 The Products should be manufactured in compliance with general safety requirements in accordance with GOST 12.0.230, GOST 12.1.004 and GOST 12.1.005.

4.3 Production facilities should be equipped with general and local suction and exhaust ventilation in accordance with GOST 12.4.021 and [1].

4.4 Employees should be equipped with personal protective equipment in accordance with GOST 12.4.011.

4.5 Wastes generated during products the manufacture are stored in collection containers and disposed of in the provided manner. Environmental pollution by production wastes is prohibited.

5 MARKING REQUIREMENTS

5.1 The Products marking should comply with the requirements of GOST R 50444 and should contain:

- trademark of the manufacturer;
- name of the manufacturer
- manufacturer's address;
- product name;
- year of the product manufacture (or the last two digits);
- designation of technical specification for the product;
- the inscription “non-sterile”;
- the inscription “disposable”.

The marking should be applied to the label. The label should be put into each packaging.

5.2 The consumer packaging marking should contain the following information:

- trademark of the manufacturer;
- the type name or designation (type, model) of the product;
- the number of products (in case of multiple packaging);
- year and month of packaging;
- designation of technical conditions;
- disposability;
- the inscription “non-sterile”;
- the inscription “disposable”.

5.3 The consumer packaging marking in case of multiple packaging should contain:

- trademark of the manufacturer;
- name or designation of the product type;
- number of products.

5.4 Marking is performed with printing or die-line copying. Inscriptions containing data on the products manufacture and preservation number, month and year, are allowed to be performed by hand.

5.5 Transport marking of packages is in accordance with GOST 14192.

6 PACKAGING REQUIREMENTS

6.1 Packaging should provide protection against mechanical and climatic

factors during transportation and storage, as well as the most complete use of the load-carrying capacity (capacity) of vehicles and the convenience of loading and unloading.

6.2 Products should be packed in plastic bags of equal sizes with labels attached to them (or pasted on them).

6.3 Bags have a size of 1400x90 mm. The weight of one package should not exceed 40 kg.

6.4 The products or products sets of various items are allowed to be packed in one package.

6.5 The packaging of products intended for export should comply with the requirements of GOST R 50444, the terms of the contract between the company and foreign economic standards.

6.6 Packaging of the products intended for shipment to the Far North and hard-to-reach areas - in accordance with GOST 15846.

6.7 Consumer packaging with packaged products should be tied with twine in accordance with GOST 17308 or glued with paper tape in accordance with GOST 18510, GOST 23436 or GOST 2228, sealing tape on a paper base in accordance with GOST 18251 - or with plastic tape with an adhesive layer in accordance with GOST 20477 so that it could not be opened without violating the integrity of the package.

When packaging products intended for transportation and storage in areas with a tropical climate, consumer packaging should be preservative treated in accordance with the terms of the contract between the company and the foreign economic organization or enterprise and the consignee.

6.8 Operational documents should be enclosed in an envelope or bag of plastic film in accordance with GOST 10354.

6.9 Operational documents should be enclosed to the consumer packaging with the product.

7 ACCEPTANCE RULES

7.1 The products are accepted in accordance with GOST R 50444.

7.2 The products are provided for acceptance in batches. The number of

products of one name, one unit size, filed with a single quality document, are a batch.

Batch size can be set by agreement with the consumer.

7.3 The following tests should be performed:

- qualification (QT);
- acceptance tests (AT);
- repeated (RT).

7.4 Qualification tests of selected samples should be performed in full, set for repeated tests.

7.5 Acceptance tests are performed by the complete inspection method.

7.6 Repeated tests should be performed at least once a year.

7.7 Incoming materials and semi-finished products control is performed in accordance with the requirements of this technical specification.

7.8 In case of unsatisfactory results, measures are taken to eliminate defects, and then the products are provided for retesting. Upon receipt of unsatisfactory results of repeated tests, acceptance should be terminated until the causes of defects are clarified and eliminated.

7.9 Controlled parameters by tests type are provided in the table 4.

Table 4

Tested Characteristics	TS clause No. of		Test type	
	Requirements	Test methods	Acceptance	Repeated

Compliance with requirements of regulatory documents	2.1	8.1	+	+
Check of document set compliance	2.5	8.2	+	+
Geometric dimensions	2.2	8.3	+	+
Control of appearance and sewing quality	7.1-7.9	8.4	+	+
Check of the set shelf-life	9.2	8.5	–	+
Mechanical effects during transportation	9.4	8.6	–	+
Thermal effects during application, transportation, and storage	9.2	8.7	–	+
Requirements to raw materials, purchased goods	2.3	8.8	+	+
Scope of supply, marking, packing	2.5, 5.1, 6.1-6.9	8.9	+	+

7.10 If nonconformities of at least one indicator are found during the acceptance tests, the tests for this indicator are repeated for doubled number of Products.

7.11 Products that have passed the acceptance tests are subjected to repeated tests.

The repeated tests for compliance with all requirements of this technical specification are performed at least once a year. Verification of the Products designated resistance against climatic effects during transportation is performed on samples of the consistency batch, as well as when changing materials, manufacturing techniques, packaging, which can cause a decrease in the resistance of the Products to the above factor.

7.12 If nonconformities of at least one indicator are found during the repeated tests, the tests are repeated for doubled number of Products. The results of repeated tests are final and are applied to the entire batch.

The results of the repeated tests are filed in the protocol.

7.13 In case of unsatisfactory results of repeated tests, the batch should be

rejected.

7.14 The results of repeated tests are final and are applied to the entire batch.

7.15 The sale of off-quality or defective products is prohibited

7.16 Qualification tests (tests of the consistency batch) are performed in full, set for periodic tests.

8 CONTROL METHODS

8.1 The control conditions should comply with normal climatic conditions in accordance with GOST 15150. The list of equipment required for testing is provided in Annex B.

8.2 Verification of compliance with the set of documents is performed during operational control by comparison with the documents.

8.3 Control of geometric dimensions should be performed with a measuring ruler under GOST 427 or a metal measuring roulette in accordance with GOST 7502, or another tool with an accuracy of ± 2 mm.

8.4 The appearance, sewing quality should be controlled visually, in daytime diffused lighting and with a special tool.

8.5 The expiration date is verified by dispatching for control storage with subsequent verification of compliance with this technical specification, as well as by the method of controlled operation or by collecting and processing the statistical information.

8.6 The resistance to mechanical stress should be tested in accordance with GOST R 50444, after which the products are checked for mechanical damage.

8.7 The product's resistance to climatic effects during operation, transportation and storage should be checked in accordance with the requirements of GOST R 50444.

8.8 Sanitary and hygienic characteristics of materials should be checked during incoming control, and in case of absence of proper information - according to GOST R 52770.

8.9 The scope of supply, marking and packaging should be checked visually, taking into account the requirements of design and technological documents.

8.10 The air permeability should be determined in accordance with GOST 12088.

8.11 Efficiency of bacterial filtration should be in accordance with GOST R EN 779.

8.12 Pressure drop between the outer and inner surfaces during inspiration or expiration should be in accordance with GOST 12.4.005.

8.13 Splash resistance should be in accordance with GOST R ISO 22958.

9 TRANSPORTATION AND STORAGE REQUIREMENTS

9.1 The products should be transported in packaging in covered vehicle (road, rail, air or water) in accordance with the procedure set by the conditions of 5 GOST15150. When transporting, loading and unloading products, measures should be taken to prevent damage to their packaging and the products moisturizing.

Shipment type is by postage, cars, railway transport in accordance with GOST 20435.

9.2 Finished Products are stored in packaging, in premises under the conditions of 2 GOST 15150.

Storage conditions should exclude exposure to moisture and aggressive media.

9.3 Loading, fixing, transportation and unloading of the products should be performed in accordance with GOST 12.3.009 and the rules for this type of vehicle in force.

9.4 Measures should be taken to prevent damage to their packaging and the products moisturizing during transportation, loading and unloading of the products.

10 APPLICATION INSTRUCTIONS

10.1 The product should be used in strict accordance with the application instructions.

11 DISPOSAL REQUIREMENTS

11.1 The used products should be disposed of as class A wastes in accordance with [2].

12 MANUFACTURER'S WARRANTIES

12.1 The manufacturer shall guarantee the buyer the preservation of all technical characteristics of the product for 12 months, subject to the above rules of handling.

12.2 The manufacturer shall not be responsible for products with mechanical damage resulting from transportation or as a result of improper use.

12.3 The warranty period is calculated from the sale date. If the sale day cannot be determined, then the warranty period is calculated from the manufacture date.

Annex A

(reference)

List of Standards and Technical Documentation (STD),
Referenced in the Technical Specification

Document Designation	Document Name
GOST 12.0.230-2007	Occupational safety standards system (OSSS). Safety management system. General requirements (with Changes No. 1)
GOST 12.1.004-91	Occupational safety standards system (OSSS). Fire safety. General requirements (with Changes No. 1)
GOST 12.1.005-88	Occupational safety standards system (OSSS). General Sanitary Requirements to Industrial Zones Air (with Changes No. 1)
GOST 12.3.009-76	Occupational safety standards system (OSSS). Loading and unloading operation. General safety requirements (with Changes No. 1)
GOST 12.4.005-85	Occupational safety standards system (OSSS). Self-contained self-rescue device. Breathing resistance value determination method
GOST 12.4.011-89	Occupational safety standards system (OSSS). Safety equipment. General requirements and classification.
GOST 12.4.021-75	Occupational safety standards system (OSSS). Ventilation systems. General requirements (with Changes No. 1)
GOST 427-75	Metal measuring rulers. Technical specification (with Changes No. 1, 2, 3)
GOST 2405-88	Manometers, vacuum gauges, pressure and vacuum gauges, U-tube manometers, draft meter and draft and head gauge. General technical specification
GOST 2228-81	Bag paper. Technical specification (with Changes No. 1, 2, 3)
GOST 7502-98	Metal measuring roulettes. Technical specification
GOST 10354-82	Polyethylene film. Technical specification (with Changes No. 1, 2, 3, 4, 5)
GOST 12088-77	Textile materials and products of them. Air permeability determination methods (with Changes No. 1, 2)
GOST 14192-96	Marking of freight (with Changes No. 1, 2, 3)
GOST 15846-2002	Products exported to areas of the Far North and equivalent areas. Packaging, labeling, transportation and storage
GOST 17308-88	Cords. Technical specification

Document Designation	Document Name
GOST 18251-87	Sealing tape on paper base. Technical specification (as Amended)
GOST 18510-87	Writing paper. Technical specification (with Changes No. 1, 2, 3 as Amended)
GOST 20435-75	Multipurpose closed metal container of 3.0 t rated gross weight. Technical specification (with Changes No. 1, 2, 3, 4)
GOST 20477-86	Polyethylene band with adhered layer. Technical specification (with Changes No. 1)
GOST 23436-83	Cable paper for insulation of power cables of 35 kV voltage inclusive. Technical specification (with Changes No. 1, 2, 3)
GOST 31508-2012	Medical Products. Classification in accordance with potential risk of use. General requirements.
GOST R 1.3-2018	The Russian Federation Standardization. Products Technical specification. General requirements for content, design, designation and updating
GOST R 50444-92	Medical devices, apparatus and equipment. General technical specification (adopted as an interstate GOST 20790-93 standard) (with Changes No. 1, 2)
GOST R 52770-2016	Medical Products. Safety requirements. Methods of sanitary-chemical and toxicological tests
GOST R ISO 22958-2011	Textile materials. Water resistance. Rain test. Exposure to horizontal splashing rainwater.
GOST R EN 779-2014	General Purpose Air Filters. Determination of technical characteristics.
GOST ISO 10993-1-2011	Medical Products. Assessment of medical products operation. Part 1. Assessment and examination.

REFERENCE LITERATURE

[1] SNiP 41-01-2003 Heating, ventilation and conditioning

[2] SanPiN 2.1.7.2790-10 “Sanitary-Epidemiological Requirements for Medical Wastes Handling”

Revision History Sheet									
Sheets (pages) numbers					Total sheets (pages) In the document	Doc. No.	Input No. of accomp. doc. and date	sign.	date
rev.	changed	replaced	new	annuled					

FARMTREST
LIMITED LIABILITY COMPANY

APPROVED BY
the Acting Director of
FARMTREST OOO
_____ S.V. Klimov
“____” _____ 2019

APPLICATION INSTRUCTION

DISPOSABLE MEDICAL PRODUCTS OF FLUSHED FABRIC: MASKS, SCRUB HATS

14.19.32-01-19152126-2019 AP

2019

TABLE OF CONTENT

INTENDED USE

Medical masks and scrub hats are intended for external use as personal protective equipment for respiratory organs, skin surface, hair.

Medical masks and scrub hats can be used at medical and preventive treatment facilities of any profile, including at dental, ophthalmological and children's hospitals, at maternity hospitals and obstetric clinics (including neonatology), clinical, microbiological and other laboratories, at blood transfusion stations, in ambulances and hospital transport, at the disaster medicine services, at the medical services of the MD, MIA, FSS, MDC at social security institutions, at children's, school and preschool institutions, at beauty salons and hairdressers, at catering and trade enterprises, utilities, by the population at home, and others. The use is allowed in the presence of patients (including children) at maternity hospitals, children's institutions.

Protective masks should also be worn, when there is a risk of infection. These are the places of mass gathering during outbreaks.

Medical scrub hats are designed to protect the user's hair and maintain the premises cleanliness and hygiene. The main purpose of this product is to protect the hair from environmental effects, as well as to protect the environment (premises or objects) from small particles spread from the head or hair.

BASIC TECHNICAL CHARACTERISTICS

The products comply with the requirements of GOST R 50444, TS 14.19.32-01-19152126-2019 and are manufactured in accordance with the technological regulation No. P 001-17 approved by the manufacturer.

The category depending on the potential risk of use is 1 in accordance with GOST 31508-2012

The type of climatic category is NF 4.2 in accordance with GOST 15150.

The category depending on the possible consequences of failure is B in accordance with GOST R 50444-92.

Opening an individual package - a barrier bag - does not require scissors.

The main parameters and technical characteristics for the medical product “Mask” are as follows:

Layers number	3
Fixation type	shirring
Antibacterial layer	melt-blown
Nose clamp	available
Dimensions, (mm), LxW	175x95
Effectiveness of bacterial filtration, at least	95 %
Specific pressure, no more than mmAq/cm^2	3

The product structure consists of 3 layers:

1st layer — spunbond (hydrophylic), weight 22 g/m².

2nd layer — melt-blown — antibacterial filter, weight 20 g/m².

3d layer — spunbond (hydrophylic), weight 27 g/m².

The protective mask has a shape with 3 folds.

Fold width, mm	15

Pressure drop between the external and internal surfaces during inhale and exhale, mmAq/cm^2, no more than 2

Nose clamp size, mm	70
Fixing shirring length, cm	
Static	16
Stretched	35
Splashes resistance, mmHg, at least	120
Seam width, cm	0.5-0.7
Fixing shirring diameter, mm	1.8
Fixing shirring length, cm	16.5±1

Basic parameters and technical characteristics for the medical product “scrub hat” are as follows:

Air permeability, dm^3/cm^2*sec, at least	210
Two-lane shirring width, mm, at least	4
Seam width, cm	0.5-0.7
Fixing shirring diameter, mm	1.8
Fixing shirring length, cm	23±1

DIMENSTIONS RANGE

• Medical disposable mask;
• Medical masks for special purposes;
- Charcoal medical mask;
- Oxygen medical mask;
• Disposable medical scrub hats of “Beret” type;
Protective masks are classified in accordance with several criteria.
- the number of layers: 1 - 4 layers;
- the color of the product: pink, white, green, blue, black, orange;
- user’s age: adults, children;
- sterility degree: sterile and non-sterile.

RECOMMENDED INDICATIONS

Medical masks and scrub hats are used for their intended purpose.
Rules for medical masks and scrub hats usage are as follows:
1. A medical mask/scrub hat is used once.
2. Wear the mask so that it covers the mouth, nose and chin.
Wear the scrub hat on the head so that it completely covers the hair, you need to straighten it for convenience.
3. If there are ties on the mask/ scrub hat, they should be tied firmly.

4. If there is a sewed in fixation in the nose area (for mask), it should be attached firmly to the back of the nose.

5. If there are special folds on the mask, they should be unfolded, providing the mask with more applicable shape for fitting tight to the face.

6. When using a mask/scrub hat in the surgery block, delivery room, dressing room, you should avoid touching it with your hands.

7. In case of touching the mask, you need to wash your hands or treat them with a skin antiseptic.

8. If the mask/scrub hat became wet, it should be replaced with a clean and dry one. Change masks/scrub hats at least each 2 hours.

9. In case of blood or other biological fluid contact with a mask/scrub hat, replace the mask with another one.

10. Used masks/scrub hats should be sterilized, as class B or C wastes category.

PRODUCT MAKEREADY

Open the package manually, take the product out and unfold it.

PRODUCT OPERATING PROCEDURES

Medical masks are designed to eliminate or reduce the causative agent exhalation from the respiratory tract, and to prevent others ingress of infection. Bring personal protective equipment, “masks” can be used to prevent the patient’s biological fluids from reaching the skin and oral and nose mucous membranes during various medical procedures and surgical interventions. The structure of these masks implies the availability of special water-resistant materials.

The mask should be worn carefully so that it tightly covers the mouth and nose, and there are as few gaps between the face and the mask as possible.

The scrub hat requires the corrugated strip (pleat) to be opened with the fingers, then put it on the head so that the scrub hat completely covers the hair, straighten it for convenience, use as intended.

After work completion, discard the used medical product and the opened individual packaging (bag) into a container for medical wastes. Masks and scrub hats should be disposed in accordance with the Decree of the Chief State Sanitary Doctor of the Russian Federation dated December 9, 2010 No. 163 “On approval of SanPiN 2.1.7.2790-10 Sanitary-epidemiological requirements for the medical wastes treatment”.

STORAGE, OPERATION AND TRANSPORTATION REGULATIONS

Packaged products should be stored away from sunlight, fire.

The climatic design category in accordance with GOST R 50444-92 is NF 4.2 - “from +10 °C to +35 °C; humidity 80% at 25 °C”;

Storage and transportation conditions for napkins should comply with GOST 15150-69: climatic conditions of transportation - in accordance with storage conditions 5, climatic conditions of storage - in accordance with storage conditions 1 (L) away from sunlight, fire.

The shelf life of the product in unopened individual packaging subject to storage conditions is 5 years.

Do not reuse, for single use only.

Do not use with damaged packaging.

Do not use medical products that have mechanical damage that violate the integrity of the product.

Revision Data Sheet

Rev.	Record date	Document Designation	Changes Content	Position, Surname, signature, date	Entry on Changes in		Note
					the original	the copy	
1	2	3	4	5	6	7	8

Testing Laboratory of ALISTOR LLC
8, MOLODEZHNAYA STREET, UNIT 2/ROOM 10, KHIMKI, MOSCOW REGION, 141407
Attestation certificate No. РОСС RU.31112.ИЛ0033 dated March 26, 2019

APPROVED
by the Head of
the Testing Laboratory of
ALISTOR LLC
/*signature*/ Varakina V.A.
January 31, 2020
*/seal: Limited Liability Company * MR * Alistor * OGRN 1195053002836/*

TEST REPORT
No. 31112/20-Я/ALS-ИЛ – 00123 dated January 31, 2020

Disposable medical products of flashspun fabric: “Products”, “Scrub hats”, “Masks”.

Customer: FARMKOM PRODUCTION ASSOCIATION Limited Liability Company. Address: 1, Montazhnikov street, BUILDING 7, the town of Novouralsk, Sverdlovsk region, 624130, OGRN: 1176658078410, telephone: 79222113366, e-mail: farmtrest@bk.ru.

Manufacturer: FARMKOM PRODUCTION ASSOCIATION Limited Liability Company. Address: 1, Montazhnikov street, BUILDING 7, the town of Novouralsk, Sverdlovsk region, 624130, OGRN: 1176658078410, telephone: 79222113366, e-mail: farmtrest@bk.ru.

Tests were held in the testing laboratory of ALISTOR Limited Liability Company. 8, Molodezhnaya street, unit 2/room 10, Khimki, Moscow region, 141407.

Measuring instruments and testing equipment comply with specifications of Alistor TL. For all units of testing equipment valid certificates are available, and calibration certificates – for measuring instruments.

Code of regulatory documents for the products: TS 14.19.32-001-19152126-2019 “DISPOSABLE MEDICAL PRODUCTS OF FLASHSPUN FABRIC”.

Testing Laboratory of ALISTOR LLC
8, MOLODEZHNAYA STREET, UNIT 2/ROOM 10, KHIMKI, MOSCOW REGION, 141407
Attestation certificate No. РОСС RU.31112.ИЛ0033 dated March 26, 2019

Test results:

The following terms are accepted:
C – the product complies with the tested requirement set by the RD.
N – the product does not complies with the tested requirements set by the RD.
NA – this requirement of the RD is not applicable to the tested product.

Tested characteristics	TU clause No.		Test results	Findings
	Requirements	Test methods		
Compliance with requirements of regulatory documents	2.1	8.1	**The requirement is met**	**C**
Check of document set compliance	2.5	8.2	**The requirement is met**	**C**
Dimensions	2.2	8.3	**The requirement is met**	**C**
Control of appearance and sewing quality	7.1-7.9	8.4	**The requirement is met**	**C**
Check of the set shelf-life	9.2	8.5	**The requirement is met**	**C**
Mechanical effects during transportation	9.4	8.6	**The requirement is met**	**C**
Thermal effects during application, transportation, and storage	9.2	8.7	**The requirement is met**	**C**
Requirements to raw materials, purchased goods	2.3	8.8	**The requirement is met**	**C**
Complete set, marking, packing	2.5, 5.1, 6.1-6.9	8.9	**The requirement is met**	**C**

The tests were held by:
Test Engineer /signature/ Zimina E.V.
position last name, initials

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