INSTRUCTIONS FOR USE
of the Medical Device
Single-use respiratory protection equipment
Medical face mask

TS 32.50.50-001-40393587-2020

1 Intended purpose

Intended purpose: creating the filtering barrier to prevent penetration and incidence of airborne infections into respiratory organs.
Area of application: can be used by medical personnel and by the inpatients, out-patients of the health care institutions, and by persons at high risk of being exposed to diseases during epidemical period or infecting other persons; in public places and trade organizations, on transport, during epidemics, in emergency situations, and in everyday use.
The potential risk of the application of medical devices class according to nomenclative classification of medical devices – 1 (Order of the Ministry of Health of the Russian Federation No. 4n "On approval of nomenclative classification of medical devices" dd.06.2012).

2 Basic technical specifications

Mask is a non-sterile single-use medical device in a form of a square topped napkin, made of non-woven materials, with sewed in nose wire, equipped with ear loops (elastic cords), with or without edging.
The shape and design of the mask provide necessary protection, dynamic compliance with anatomical peculiarities of nasal-oral facial area and do not cause discomfort while using.
The medical mask consists of 3 layers:

- 1st layer (near face, undyed) - spunbond (hydrophobic);
- 2nd layer - filtering (SMS, SMMS, Meltblown) - bacteria-excluding filter;
- 3rd layer (outer, dyed) - spunbond (hydrophilic).

Bacterial filtration efficiency must be not less than 98%.
Air permeability (differential pressure) must be not more than 29.4 Pa/cm^2.
The medical mask has three folds, from 1 to 1.2 cm in depth.
There is a sewed in nose wire (clamper) on the top of the mask 90-110 mm in length of plastic, reinforced-plastic or metal-paper strip for better fitment of the mask in the area of the nose bridge due to following the nose shape.
The mask is equipped with restraints – elastic ear loops that provide tight fitment of the mask to the face on each side, molding nose, mouth and chin of the user.
Mask elements are braced mechanically via ultrasonic welding.
The mask must not disintegrate, destruct or tear while using.
The device corresponds to Ambient class type NF 4 according to Government Standard GOST 15150.

Requirements for physic-mechanical, sanitary-chemical and toxicological parameters:

Parameter name	Parameter value
pH-value, pH units	**(6,00 - 9,00) ± 1,00**
Ultraviolet absorption, OA units, NMT	**0,300**
Reducing impurities, dm^3, NMT	**1,00**
Formaldehyde content, mg/dm^3, NMT	**0,100**
Acetic aldehyde content, mg/dm^3, NMT	**0,200**
Acetone content, mg/dm^3, NMT	**0,100**
Methanol content, mg/dm^3, NMT	**0,200**
Isopropanol content, mg/dm^3, NMT	**0,100**
Bacterial filtration efficiency, %	**> 98**
Air permeability (differential pressure), Pa/cm^2	**< 29,4**
Microbial limits, CFU/g	**< 30**
Irritation test, points	0
Sensitizing action, points	Negative provocative intradermal test

3 Device designs

A) Single-use respiratory protection medical face mask, size (width x length) 8.0 cm x 14.5 cm.
B) Single-use respiratory protection medical face mask, size (width x length) 9.0 cm x 14.5 cm.
C) Single-use respiratory protection medical face mask, size (width x length) 10.0 cm x 17.5 cm.

4 Delivery set

5 or 10 one size masks in a polymeric package; or 50 pcs. in a carton box.
Instructions for use (leaflet).

5 Indications for use

Use as intended in order to comply with public health requirements in the instances provided by the area of application.

6 Contra-indications

- Idiosyncrasy of mask materials (predisposition for allergies)
- Expired shelf life
- Mechanical damage of devices within a delivery set

7 Side-effects

Allergic response in case of mask materials idiosyncrasy may occur.

8 Pre-starting procedures

1. Check the shelf life applied to the package: if the shelf life is expired, the device is unsuitable for use.
2. Open the package; take the device out of the package.
3. Attach the mask with the undyed side to the face, with rigid wire to the nose bridge.
4. Place ear loops around the ears.
5. Straighten out the mask folds to cover the nose, mouth and chin tightly.
6. Mold the nose wire (clamper) to the nose bridge.

The mask provides the protective function within 2 hours. It is recommended to replace the mask after the expiry of the specified time.
After using the mask, dispose of it according to the current instructions.

9 Requirements for technical maintenance and repair of the medical device:

Single-use product, beyond repair

10 Storage and transportation

Store in original package at temperature +10 °C to +35 °C and relative humidity of NMT 80%, protect from the exposure to atmospheric precipitations and direct sunlight. Storage conditions -1 (Л) according to Government Standard GOST 15150.
Transportation conditions - 5 according to Government Standard GOST 15150.
The device may be transported by all kinds of closed vehicles if they are protected from contamination and mechanic damage, in accordance with the shipping rules applicable for this kind of vehicle.
The mask must be resistant to mechanic damage during transportation, according to Government Standard GOST R 31209.

Guaranteed shelf life is 4 years from the manufacturing date.

11 Recycling

Unused masks, as intended, with the expired shelf life, with the damaged package, in accordance with Sanitary Rules and Regulations SanPiN 2.1.7.2790-10, are utilized according to the procedure provided for municipal solid waste.
Used masks belong to class B of medical waste and are utilized in accordance with Sanitary Rules and Regulations SanPiN 2.1.7.2790-10 “Public health requirements for medical waste management”. Dispose of the package with municipal solid waste.
* Natural persons shall dispose of the used masks in containers for municipal solid waste, after preliminary putting the mask in a separate airproof package (or the original package).
** Mask disposal in organizations:
The used masks must be collected in a single-use soft package (bags) or solid (puncture resistant) package (containers) of yellow color or with yellow labeling.
Soft package (bags) must be fastened on special cart stands or containers.
After filling the bag by not more than ¾, the employee who is responsible for waste collection at this medical organization fastens up the bag and seals it using tie-wraps or other fixtures that exclude the spilling.
Masks are put in containers in closed packages (bags) and brought to the waste management area or in the room for temporary storage of medical waste for next shipment by specialized organizations vehicles to the disinfecting / deactivation place.

12 Packaging

5 or 10 pcs of one size masks in a labeled polymeric bags or 50 pcs in carton boxes.
Polymeric bags or carton boxes are put in a multiple packaging – a corrugated container. 1000 or 2000 masks in a multiple packaging.

13 Manufacturer, manufacturing address:

The Federal State Unitary Enterprise “Moscow Endocrine Plant”
Russia, 243413, Bryansk region, Pochepskiy municipal region, municipal settlement Ramasukhskoye, Northern industrial zone territory, building 2/2A, building 2/2B.

Organization for receiving consumer claims:

The Federal State Unitary Enterprise “Moscow Endocrine Plant”
Russia, 109052, Moscow, Novokhokhlovskaya str., 25
Tel./fax: (495) 678-00-50 / 911-42-10
http://www.endopharm.ru

THE DEVICE IS NON-STERILE, STERILIZATION IS NOT APPLICABLE BEFORE USE
NON-TOXIC

SINGLE-USE DEVICE, CANNOT BE REUSED

Marketing authorization No. P3H 2020/10280 dd. 08.05.2020

14 Graphical characters used for spotting onto labeling

Character image	Character name
	Storage temperature
	Keep dry
	Protect from direct sunlight
	Read and understand the instructions for use
	Not a nutrition product
	Can be utilized together with household waste