

Technical Data Sheet

OPERATIONAL DOCUMENTATION of the medical device

MEDIWISH Dental set disposable sterile

Produce by «Mediwish Co., Ltd.»



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1. BASIC INFORMATION ABOUT THE MEDICAL PRODUCT

1.1. Name of medical device

MEDIWISH Dental set disposable sterile

1.2. Manufacturer

Mediwish Co., Ltd

Address: Tianhe Street, Building 336, Luyang Industrial Zone, Hefei City, People's Republic of China.

1.3. Purpose of a medical product

Designed for primary dental procedures, mass primary and preventive examinations in dental offices, clinics and medical institutions, on-site examinations and dental procedures in emergency cases when it is impossible to provide emergency sterilization of dental tools and workplaces, as well as during dental offices in field and military conditions.

The medical device may only be used by qualified dentists.

1.5. Application area

Dentistry

1.6. The composition of the medical product

The set of dental instruments includes:

1. MEDIWISH Tray
2. MEDIWISH Mirror
3. MEDIWISH Probe
4. MEDIWISH Tweezers
5. MEDIWISH Napkin

1.7. Materials of the component parts of the medical device

Information on the materials of the component parts of the medical device - MEDIWISH A one-time, sterile dental instrument set is shown below in Table 1

Table 1

Full product name: specific product position or affiliation	Material specific position of the product or its accessories	Body contact	Sterility Information
Holder and head for MEDIWISH Mirror; Pen for MEDIWISH Probe; Base and Branches for: MEDIWISH Tweezers	<i>Made from: PVC brand YFY-A-79, white unpainted, Colored Blue, dye brand JZ-17</i>	Do not have contact with the oral mucosa of the patient. The medical staff is wearing gloves.	sterile

Metal rods for: MEDIWISH Probe; Metal tips for MEDIWISH Tweezers;	<i>Made from: Stainless steel AISI 304, chemical composition (%): Carbon (C) - up to 0.8, Silicon (Si) - up to 0.8, Manganese (Mn) - up to 0.2, Nickel (Ni) - 9-11, Sulfur (S) - to 0.02, Phosphorus (P) - to 0.035, Chromium (Cr) - 17-19, Titanium (Ti) - to 0.5, Copper (Cu) - to 0.3, Iron (Fe) ~ 69, unpainted.</i>	Short-term contact with the intact oral mucosa of the patient The medical staff is wearing gloves.	sterile
MEDIWISH plastic tray	<i>Made from: PVC brand KAY -07Z, white unpainted color</i>	Do not have contact with the oral mucosa of the patient. The medical staff is wearing gloves.	sterile
MEDIWISH napkin	<i>Made from: A single layer of MXPT009 colored cellulose paper, color blue. dye brand JZ-17 The second layer of plastic film brand YST-PW-012, unpainted</i>	Do not have contact with the oral mucosa of the patient. The medical staff is wearing gloves.	sterile
Consumer (individual) packaging	<i>The film coating (transparent side) is made of a polyethylene film of the brand MW 170, thickness (mm): 0.05 - 0.3 in increments of 0.01 mm and connected with a thermal seam to high-strength, medical kraft paper (80 g / m²) (opaque side), varnished (10 g / m²), thickness (mm): 0.07 - 0.3 with a pitch of 0.01 mm.</i>	Do not have contact with the oral mucosa of the patient. The medical staff is wearing gloves.	Sterile inside

1.8. List of international standards with which a medical device complies

Table 2

Nº documents	Date of adoption	Name
Council Directive EC 93/42	14 June 1993	Council Directive 93/42 on medical devices
Council Directive EC 2007/47	05 september 2007	Council Directive 2007/47 / EC on medical devices
EN ISO 13485:2016	01 march 2016	"Medical Products. Quality management systems. Requirements for regulatory purposes "(Medical devices. Quality

		management systems. Requirements for regulatory purposes)
ISO 9873-2011	01.01.2013	Stomatological hand tools. Mirrors and pens to them reusable

1.9. Description of the medical product

A medical device is a disposable, sterile set of dental instruments that can be used in almost all types of dental procedures.

This set of disposable instruments is designed to make dental examinations and the necessary dental procedures safe and easy. Such kits are useful for outpatient care, in nursing homes, in clinics. First of all, they provide protection both to the patient and the health worker from diseases transmitted by means of the instruments used. For example, infectious diseases, AIDS, hepatitis. Sterile packaging ensures long-term storage of instruments and ensures their safety. Medical device for single use only.

The kit includes:

1. MEDIWISH Polymer tray for stacking components of a set, is a rectangular container, without a lid, intended for storage / sterilization / transportation within the institution of dental instruments, consumables. In hospital and laboratory conditions - for completely diverse functions. Used in dental practice. Made of non-toxic PVC.

2. MEDIWISH mirror is an instrument designed to examine teeth, carious cavities, examine the oral mucosa, protect soft tissues from injury and fix the tongue, cheeks and lips while examining the patient. It provides a realistic image. The mirror consists of an elongated holder (handle) and head with a working element (flat glass reflecting surface) enclosed in a frame, located in a plane oriented at an angle to the longitudinal axis of the holder (handle). The back side of the holder (handle) is made in the form of a spatula. The construction is one-piece. For ease of use, the handle of the mirror has a faceted surface and grooving for fingers. Made of non-toxic PVC.

3. MEDIWISH Probe is a tool designed to study the tooth surface for the presence of carious cavities, filling defects, also helping to test tartar, diagnose the condition of the fissures, reveal the presence of a message of the carious cavity with the tooth cavity, determine the degree of pain and the stage of softening of tooth tissues. It consists of a plastic handle and, attached to both ends of the handle, metal rods with pointed working areas oriented at an angle to the non-working area connected to the handle. Metal rods are thermally connected to the handle. The probe handle is made of non-toxic PVC, metal rods are made of stainless steel. For ease of use, the probe handle has a faceted surface. To avoid damage to the packaging, the working sections of the metal rods are equipped with PVC-made protective covers in the form of hollow tube sections.

4. MEDIWISH Tweezers - a tool designed to hold, move auxiliary materials in the mouth, restrain saliva and protect the mucous from drugs, diagnose the stability or mobility of the root and tooth, fixing other dental tools, grabbing, and holding the dressing material (bandages, cotton wool , tampons), tissues during manipulations. It consists of a base and two branches. Base and branches solid. Between the branches inserted strut (which gives them the properties of levers of the third kind). The working ends of the branches are wedge-shaped and are equipped with metal tips that are connected to the branches in a thermal way. Tips of tweezers for ease of use, bent at an obtuse angle, they end in jaws, slightly rounded to the end and having a notch, ensuring reliable grip of the material. From the outer side of the branches in the middle part there are supporting recesses

for the fingers with longitudinal ribs. A clamping mechanism is located on the inside of the branch to prevent lateral displacement of the closed jaws. The back side of the base has a decorative branching. To avoid damage to the packaging, the metal tips of the tweezers are equipped with PVC-made protective covers in the form of hollow tube sections.

5. MEDIWISH Napkin - is a rectangle with a neckline for girth of the patient's neck, made of two layers of cellulose paper and one layer of film made of high-pressure polyethylene. The edge of the cutout is treated with a bake of fluellin, ending on both sides with strings. The napkin is designed to maximize the protection of the patient's clothes from contamination during dental procedures and medical procedures and to provide a barrier against moisture.

1.9.1. Indications for use

Application in the field of dentistry for examination, diagnosis of teeth and soft tissues of the oral cavity, carrying out various manipulations in the oral cavity. Prevention and protection against cross-infection.

1.9.2. Contraindications

There are no contraindications for the use of a medical product.

1.9.3. Possible side effects

Use of a MEDIWISH Dental set disposable sterile does not affect the process of mutual conditioning and communication of medical devices.

1.9.4. Interaction with other medical products

Use of a MEDIWISH Dental set disposable sterile does not affect the process of mutual conditioning and communication of medical devices.

1.9.5. Frequency and features of use of the medical product

Disposable product

2. MAIN TECHNICAL CHARACTERISTICS

A medical device is a disposable, sterile set of dental instruments that can be used in almost all types of dental procedures. Sterile packaging ensures long-term storage of instruments and ensures their safety. Consumer (individual) packaging is a package. Overall dimensions (length x width) 260 mm x 160 mm \pm 2 mm. The width of the weld is not less than 0.8 mm, the thickness of the weld is 0.10 mm \pm 0.03 mm.

The mass of the medical device in a package is not more than 70 g.

Kit Components:

1. MEDIWISH Polymer tray for stacking components set.

Made of non-toxic PVC.

Overall dimensions (along the upper edge): length - 190 mm \pm 5 mm, width - 125 mm \pm 5 mm, height - 20 mm \pm 5 mm. Tray weight 10 \pm 5 g.



2. MEDIWISH Mirror

Made from non-toxic PVC.

The head has a diameter of 25 mm \pm 2 mm and a ring-shaped continuous holding section with a width of not more than 2 mm on the working part. The working part is flat, glass reflective surface made of polished glass.



On the surface of the working part there should be no visible defects such as waves, chips, scratches and other defects visible to the naked eye. The reflective surface should not have image distortions. The holder has a length of 105 mm \pm 2 mm and a diameter of 6 mm \pm 2 mm. The spatula has a width in the widest part of 13 mm \pm 1 mm and a length of 37 mm \pm 1 mm. Mirror weight 10 \pm 5 g.

3. MEDIWISH Probe

The probe handle is made of non-toxic PVC, metal rods are made of stainless steel.

The total length of the probe is 205 \pm 1 mm, the handle length is 9 \pm 1 mm, the length of metal rods is 57 \pm 1 mm,



the working part of the probe is 32 \pm 1 mm. Diameter of metal rods. 1.4 \pm 0.2 mm. The bending force of metal rods is 220 N. Vickers hardness is not less than 500 HVI and the tensile strength of the working end is not less than 1700 MH mm² Probe mass 5 \pm 2 g.

4. MEDIWISH Tweezers

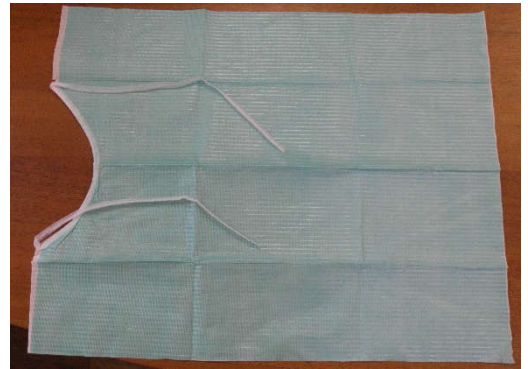
The metal tips of tweezers 25 mm \pm 5 mm long are bent at an angle of 105° \pm 10 °. Main and overall dimensions of tweezers: length - 130 \pm 1 mm, height of the curved working part - 17 \pm 1 mm, width of the jaw in the proximal part - 9.7 \pm 1 mm, distance between the ends of the branches on the inside



in the opened form - 20 \pm 3 mm Depth of basic dredging is no more than 2 mm. The amount of force for closing the jaws - no more than 5 N. Mass of tweezers 10 \pm 5 g

5. MEDIWISH Napkin - Overall dimensions of the napkin 430 x 350 ± 10 (length, width). The depth of cut for girth of the patient's neck is 45 mm ± 5 mm. The length of the strings is 250 mm ± 10 mm

There are no cracks, burrs, scratches, nicks, delamination's, spalls, paint marks, holes, etc. on the surfaces of the tray and tools. Consumer packaging - sealed.



3. COMPLETENESS OF SUPPLY OF MEDICAL PRODUCT

Are included in the package of delivery of a medical product:

1. MEDIWISH Tray
2. MEDIWISH Mirror
3. MEDIWISH Probe
4. MEDIWISH Tweezers
5. MEDIWISH Napkin
6. Individual packaging.

4. MANUFACTURER'S WARRANTIES

The manufacturer guarantees that the MEDIWISH Dental set disposable sterile that is manufactured free from defects in materials, and also guarantees its compliance with the requirements of international and national standards for the entire shelf life subject to compliance with transportation, storage rules and operating conditions in accordance with the instructions for use established by the manufacturer. The manufacturer is not responsible for the misuse of the medical device.

The warranty period of the product is 2 years from the date of issue.

5. MARKING

Marking of a medical product is carried out by applying basic data on consumer (individual) and transport (group) packaging. For marking, the symbols of DIN EN ISO 15223-1 are used, which guarantee the uniqueness of the data.

5.1. Marking of consumer (individual) packaging

The labeling of consumer (individual) packaging is printed and contains the following information:

- Name of the medical device;
- Manufacturer logo;
- Name and address of the manufacturer;
- Information about the authorized representative of the manufacturer in the territory of the Russian Federation;
- Brief description of the medical product;
- Details of completeness;
- Date of manufacture;
- Expiry date;

- Information about the warranty period of storage;
- The series and number of the Registration Certificate for a medical product
- Indication of sterility, non-toxicity, non-toxicity inside;
- Indication of prohibition of use in case of violation of the integrity of the package;
- Indication of single use;
- The symbol "Upper limit of the temperature range";
- Symbol "Sterilization with ethylene oxide";
- The symbol "Do not re-sterilize";
- "Batch code" symbol with batch number
- Symbol "Avoid exposure to sunlight"
- Symbol "Keep out of moisture"
- A mark of conformity with the requirements of EU Directive 93/42;
- Mark of Compliance (PCT) mandatory certification;












NOTE Layout labeling consumer (individual) packaging presented in Appendix A to this Statement.

38.2. Marking of transport (group) packaging

Marking of transport (group) packaging is made by printing and contains the following information:

- Name of the medical device;
- Manufacturer logo;
- Name and address of the manufacturer;
- The number of items in the package;
- Information about the authorized representative of the manufacturer in the territory of the Russian Federation;
- Brief description of the medical product;
- Details of completeness;
- Date of manufacture;
- Expiry date;
- Information about the warranty period of storage;
- The series and number of the Registration Certificate
- Indication of sterility, non-toxicity, non-toxicity inside;
- Indication of prohibition of use in case of violation of the integrity of the package;
- Indication of single use;
- The symbol "Upper limit of the temperature range";
- Symbol "Sterilization with ethylene oxide";
- The symbol "Do not re-sterilize";
- "Batch code" symbol with batch number
- Symbol "Avoid exposure to sunlight"
- Symbol "Keep out of moisture"
- A mark of conformity with the requirements of EU Directive 93/42;
- Mark of Compliance (PCT) with mandatory certification;

5.3. Identification of symbols used for labeling a medical product

№	Symbol	Decryption
1		Temperature Range
2		Avoid exposure to sunlight.
3		Do not re-sterilize
4		Mark of compliance with mandatory certification
5		Mark of conformity with the requirements of EU Directive 93/42
6		Keep away from moisture
7		Prohibition of reuse
8		Ethylene oxide sterilization
9		Batch code
10		Apyrogenic
11		Do not use if packaging is damaged.

6. OPERATIONAL INFORMATION

6.1. Mode of application

MEDIWISH Dental set disposable sterile should be used only by medical specialists with sufficient qualifications and experience in working with dental instruments.

Open the consumer (individual) package - the package by tearing off the side using a special V-shaped notch, or cutting off the side of the package - so that you can freely remove the sterile tool tray. Remove the sterile instrument tray only with sterile gloves. The assistant needs to put a protective cloth on the patient and fasten it around his neck with strings.

IMPORTANT! It is necessary to control the tensioning force of the strings in order to avoid patient's breathing difficulties

Remove from the tray the necessary tool for examining the patient's oral cavity and / or carrying out manipulations in the oral cavity. When using the MEDIWISH Tweezers and the MEDIWISH Probe, remove the protective covers from the metal parts of the tools. After using the kit - it is disposed of.

6.2. Terms of Use

The medical device is allowed to be used in the conditions of dental offices of clinics and in treatment-and-prophylactic institutions, as well as when deploying dental offices in field and military conditions. In accordance with the operating conditions:

- ambient temperature, ° C: from plus 5 to plus 25;
- relative humidity,%: from 20 to 80;
- atmospheric pressure, hPa: from 860 to 1060.

6.3. Precautionary measures

When working with the product it is recommended to use protective gloves and goggles. A disposable product, do not reuse for another patient. The kit is sterile, does not require additional sterilization and pre-preparation for use. Be careful when handling sharp and piercing objects that make up the kit.

In case of careless use and damage to the skin and mucous membranes, the site of damage should be washed with water and treated properly. Take the necessary measures to prevent viral and bacterial infections (HIV, hepatitis, etc.) and detect infection. Do not use after expiration date.

After opening the consumer (individual) packaging, the product can not be re-sterilized or reused.

In the event of damage to the individual packaging, the product should not be used, and should be returned or disposed of.

6.4. Sterility

The medical device is supplied sterile. Sterilization gas (ethylene oxide).

6.5. Transportation and storage

A set of dental instruments should be stored in transport (group) packaging in closed premises with natural ventilation in accordance with the instructions of the manufacturer's operational documentation and in accordance with the requirements of GOST 15150-69 under environmental conditions:

- temperature, ° C: from plus 5 to plus 40;
- relative humidity,%: from 20 to 80, without condensation;
- atmospheric pressure, hPa: from 700 to 1060.

During storage, protection against mechanical damage, moisture and direct sunlight must be ensured.

Transportation of a medical product in a transport (group) package must be carried out in all types of covered vehicles, in accordance with the rules of transportation operating on the transport of this type, with protection from mechanical damage and precipitation during loading and unloading. Environmental conditions during transportation comply with environmental conditions during storage.

40. MAINTENANCE AND REPAIR OF THE MEDICAL PRODUCT

The design of the medical product does not provide for the maintenance and repair of components and components throughout the warranty period.

41. ENVIRONMENTAL INFORMATION

MEDIWISH Dental set disposable sterile meets the environmental requirements established by applicable law for this type of medical product.

The product design and packaging material does not contain in its composition, and also does not emit during storage, use and disposal of harmful substances that can harm the natural environment, health and genetic resources of man.

42. INFORMATION ON THE DISPOSAL OF THE MEDICAL PRODUCT

Dispose of a MEDIWISH Denta disposable sterile, in accordance with accepted medical practice, current laws and regulations disposal.