

## Medical devices for *in vitro* diagnostics

### «96 DEEP WELL PLATE 2 ML, V-BOTTOM», «96 MAGNETIC TIP COMB»

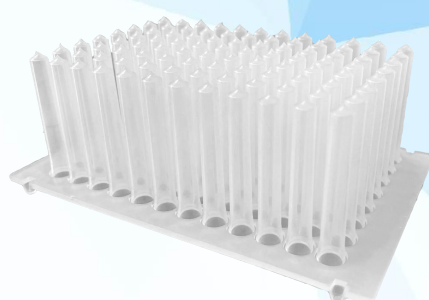
96 Deep Well Plate 2 ml, V-bottom, 96 Magnetic tip comb - disposable plastic products used for the isolation of DNA and RNA in molecular biological studies *in vitro*.  
Intended to use in medical and research laboratories.

Name of medical devices for *in vitro* diagnostics

96 Deep Well Plate 2 ml, V-bottom



96 Magnetic tip comb



Normative document

TC C 22.2-13429839-007:2021. Plastic laboratory products for *in vitro* diagnostics. Specifications.  
TF 13429839.007-2021. Technical file of a medical device for *in vitro* diagnostics. Plastic laboratory products for *in vitro* diagnostics.

Material of products  
Safety-related features

Polypropylene homopolymer - **Medical PP Purell671T**

• **physical:**

resistance to high temperatures - products remain unchanged and do not deform when heated to 100 ° C;  
resistance to low temperatures - products remain unchanged and do not deform at a temperature of minus 20 ° C;  
leakage - products do not leak;

• **biological:**

special biological state – products are free of DNases, RNases, human DNA and PCR inhibitors.

• **others:**

appearance - on the surface of the products there is no: underfilling; deformations that spoil the appearance of the product and violate its functionality; burn; cracks; blisters, local accumulations of foreign inclusions.

The expiration date and storage conditions

**Shelf life** - 3 years from the date of manufacture.

**Storage conditions:**

- store at a temperature of 1 to 35 ° C and relative humidity not more than 80% in covered warehouses at a distance of not less than 1 m from heating appliances;
- when storing, take into account the manipulation marks on the box "**Top**", "**Fragile**", "**Protect from rain**" according to DSTU ISO 780.

Compatibility with stations for automatic NA extraction

**KingFisher Flex96**, Thermo Fisher Scientific (USA);  
**Autopure96**, Hangzhou Allsheng Instruments Co., Ltd (China);  
other similar equipment, such as **Nexor96**, LepuMedical (China).

**Packaging**

*Consumer packaging*



*group packaging -*



**Deepwell plates are packed as follows:**

*Polymeric packages*

**5 products are packed in one package.**

*transport packaging*



*Corrugated box 475x285x255 mm*  
*5 carton boxes are enclosed in one corrugated box.*

***In one corrugated box there are 50 products.***

*Carton boxes 270x240x90 mm.*

*2 packages with products are enclosed in one box. In one box there are 10 products packaged in 5 pieces.*

**The combs are packed as follows:**

*Polymer bags*

**2 products are packed in one package.**

*transport packaging*



*Corrugated box 475x285x255 mm with cardboard partitions 275 x 245 mm. 50 packages with products are enclosed in one corrugated box.*

***In one corrugated box - 100 products.***

*Consumer packaging*



**Medical device safety labeling**

The labeling of a set of products (it is allowed to indicate the labeling data on the consumer packaging) must contain:

- the name of the manufacturer or its trademark of goods and services;
- Product name;
- designation of the polymeric material from which the product is made and the possibility of its recycling DSTU 4260;
- symbols "Manufacturer", "Medical device for in vitro diagnostics", "Non-sterile", "Reuse Prohibited", "Do not use in violation of the integrity of individual packaging", "Batch number", "Date of manufacture", "Use before" according to GOST EN ISO 15223-1;
- quantity;
- mark of compliance with technical regulations in accordance with the resolution of the Cabinet of Ministers of Ukraine №1184 of 30.12.2015.

**Instructions for use**

1. Condition the product in the package before use.
2. Open the consumer packaging and remove the required number of products for the test.
3. Using a pipette, add the test material and / or reagents to the wells of the tablet.
4. Set the required number of tablets and combs in the seats at the nucleic acid release station.

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**96 Deep Well Plate 2 ml, V-bottom**  
**APPEARANCE**



**Medical devices for in vitro diagnostics**

## 96 Magnetic tip comb APPEARANCE

