

## Instructions for use

ep Dualfilter T.I.P.S.® SealMax – EU IVD

English (EN)

## 1 Safety

### 1.1 Intended use

The pipette tips of the ep Dualfilter T.I.P.S. SealMax product group with the respective product numbers are designed and constructed for low-contamination transfer of liquids, in particular for samples from the human body and for reagents within the scope of an in-vitro diagnostic application in order to allow the in-vitro diagnostic medical device to be used as intended. The above mentioned ep Dualfilter T.I.P.S. SealMax are in-vitro diagnostic devices according to Directive 98/79/EC of the European Parliament and the Council dated October 27, 1998. They are intended exclusively for single use and for application by qualified staff.

### 1.2 Warnings for intended use

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**WARNING! Damage to health due to toxic, radioactive or aggressive chemicals.**

- ▶ Wear your personal protective equipment.
  - ▶ Observe the national regulations for handling these substances.
  - ▶ Observe the manufacturer's Safety Data Sheets and application notes.
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**NOTICE! Carry-over, contamination and incorrect dispensing results due to the incorrect use of pipette tips.**

The pipette tips are for single use only. Prolonged use can have a negative impact on dispensing tasks.

- ▶ Only use the pipette tips once.
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**2 Instructions for use**  
ep Dualfilter T.I.P.S.<sup>®</sup> SealMax – EU IVD  
English (EN)

**2 Product description**

**2.1 Features**

The pipette tips are single-use pipette tips for aspirating and dispensing liquids with air cushion pipettes. The packing of the pipette tips is color-coded and corresponds to the color of the control button of the respective Eppendorf pipette. The pipette tips are equipped with water-impermeable, two-phase filters. The filter protects the pipette from aerosols, liquid drops and splashes and prevents over-pipetting of liquids. If liquids with low water concentration and liquids with high salt concentration are used, the function of the filter is reduced.

**2.2 Materials**



**NOTICE! Aggressive substances may damage components, consumables and accessories.**

- ▶ Check the chemical resistance before using organic solvents or aggressive chemicals.
- ▶ Only use liquids whose vapors do not attack the materials used.

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<b>Component</b>	<b>Material</b>
Pipette tip	Polypropylene (PP)
Rack	Polypropylene (PP)

## 2.3 Packaging label

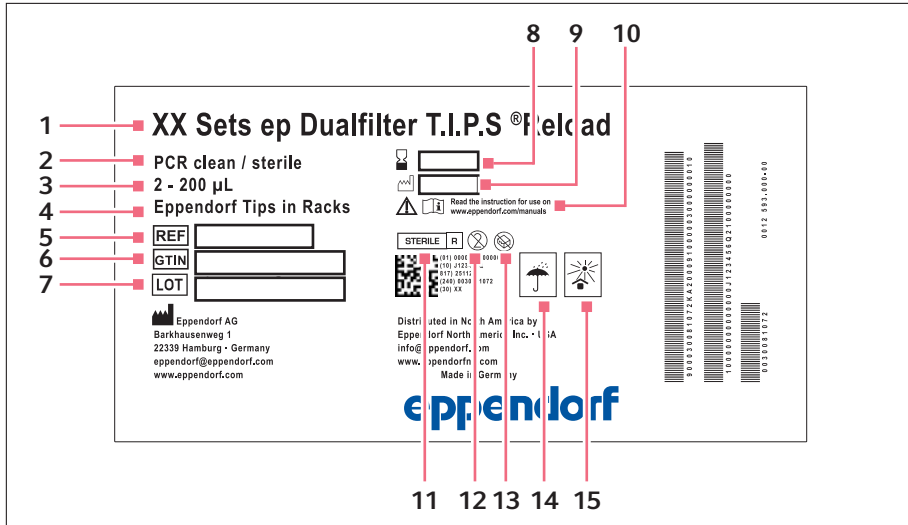


Fig. 1: Example layout



- |                                  |                                       |
|----------------------------------|---------------------------------------|
| 1 Product name                   | 9 Production date                     |
| 2 Purity grade                   | 10 Read the instructions for use      |
| 3 Volume variant                 | 11 Radiation-sterilized               |
| 4 General product description    | 12 Do not reuse                       |
| 5 Manufacturer article number    | 13 Do not use if packaging is damaged |
| 6 GTIN: Global Trade Item Number | 14 Store dry                          |
| 7 Batch number                   | 15 Protect from sunlight              |
| 8 Use by                         |                                       |

**4** **Instructions for use**  
ep Dualfilter T.I.P.S.<sup>®</sup> SealMax – EU IVD  
English (EN)

**3** **Operation**


**3.1** **Notes on operation**

Observe the descriptions in the operating manual of the pipette used.

-  Only use visually perfect and undamaged pipette tips. If the packing is damaged, do not use the pipette tips.
-  Do not use filter tips without a filter or with an incorrectly inserted filter. Do not suck liquid into the filter.

**4** **Decontamination process**

**4.1** **Autoclaving pipette tips**

-  The pipette tips are not autoclavable.

**5** **Technical data**

**5.1** **Minimum shelf life**

Product	Purity grade	Minimum shelf life
ep Dualfilter T.I.P.S. SealMax	Sterile + PCR clean	at least 5 years

The date of manufacture as well as the minimum shelf life can be found on the packaging label. The minimum shelf life is in relation to the production date.

**6** **Transport, storage and disposal**

**6.1** **Transport**

	Air temperature	Relative humidity	Atmospheric pressure
In transport packing	-25 °C – 55 °C	10 % – 95 %	70 kPa – 106 kPa

**6.2** **Storage**

Store dry at room temperature. Protect from sunlight and UV rays.


**6.3** **Disposal**

Dispose of the packing in accordance with the marking and comply with the legal regulations.

## 7 Purity grades and certificates

### 7.1 Eppendorf purity grades

The following purity grades are available for the pipette tips:

Sterile + PCR clean	 
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#### 7.1.1 Batch testing (certified) for the following purity criteria

	Sterile + PCR clean
Human DNA-free	■
DNA-free (free of human and bacterial DNA)	
DNase-free	■
RNase-free	■
PCR inhibitor-free	■
ATP-free	
Pyrogen-free (endotoxin-free)	■
Sterile (Ph.Eur./USP)	■

#### 7.1.2 ep Dualfilter T.I.P.S. SealMax

	Sterile + PCR clean
ep Dualfilter T.I.P.S. SealMax	■

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### 7.2 Certificates

There are two different categories of certificates for Eppendorf Liquid Handling consumables:

Batch-specific certificates are prepared for the following purity grades:

- PCR clean
- PCR clean and Sterile

General certificates of conformity:

- Certificate of conformity for products with the purity grade PCR clean (Certificate of Purity – PCR clean).
- Certificate of conformity regarding trace metal (Certificate of Quality – epT.I.P.S. – Typical values for trace metal).
- Certificate of conformity regarding surface active additives (Certificate of Quality epT.I.P.S. and ep Dualfilter T.I.P.S. Quality Assurance).
- EC conformity declaration (Certificate of EC Conformity Declaration – epT.I.P.S.).
- Certificate of conformity regarding the material composition and adherence to the error of measurement of pipette tips (Certificate of Quality/Conformity – epT.I.P.S. Dualfilter, LoRetention, SealMax).
- Certificate of conformity regarding the plastic granulates used (Certificate of Quality/Conformity – Laboratory Consumables).
- Certificate of conformity regarding the filters used (Certificate of Quality/Conformity – ep Dualfilter T.I.P.S. – EPA/HEPA).

All certificates can be downloaded from our website [www.eppendorf.com/certificates](http://www.eppendorf.com/certificates).



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