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Codice Fiscale e P. IVA 02405040284

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# TECHNICAL SHEET

## B4978ST

### BIOPROTEKTOR SAFETY CONTAINERS

MANUFACTURER: KALTEK SRL  
CLASSE IVD: A  
EMDN: W050301029099  
GIVD (EDMA) 51.09.10.01  
GMDN 35347



**INTENDED USE:** CONTAINER FOR BIOLOGICAL SAMPLES

CODICE	DESCRIZIONE	UDI-DI
4978	BIOPROTEKTOR 90	08055510563202
4980	BIOPROTEKTOR 150	08055510563219

#### PRODUCT DETAILS

REF.	ACTUAL CAPACITY	FORMALDEHYDE QUANTITY	LOWER Ø	UPPER Ø	HEIGHT	TOTAL HEIGHT (cap included)	MAX EMBEDDING CASSETTES CONTAINED	PACKAGING
4978	60 ml	40 ml	40 mm	45 mm	68.8 mm	102 mm	4 pcs	24 pcs
4980	150 ml	90 ml	66 mm	70 mm	71 mm	109 mm	12 pcs	12 pcs

**Closed-circuit** disposable container with screw cap, pre-filled with 4% formaldehyde solution (buffered 10% formalin) or 40% Formaldehyde diluted in ratio 1/10 (4% w/w) in phosphate solution.

The container is completely smooth to facilitate the introduction and extraction of the sample and has a knurled screw cap to facilitate opening and closing operations. Suitable for the management of biological samples during collection and transport; designed to guarantee maximum safety to the operator that is not in contact with the formaldehyde contained in the sealed capsule inside the cap. Even in case of incorrect transport (container lying on the side) the sample remains completely immersed in the fixative.

The container is manufactured with latex and phthalates free materials

CONTAINER AND CAP : POLYPROPYLENE + THERMOPLASTIC ELASTOMER (TPE-S)  
UNDER CAP : HIGH DENSITY POLYETHYLENE

#### COLOR

Container : neutral (translucent)  
Cap : pink

#### 4% FORMALDEHYDE COMPONENTS

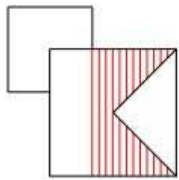
40% formaldehyde diluted in ratio 1/10 (4% w/w) in phosphate solution

Composition:

CAS 7732-18-5	DEIONIZED WATER	93-96%
CAS 50-00-0	FORMALDEHYDE	3,5 - 4,50%
CAS 67-65-1	METHYL ALCOHOL	0,1-0,2 %
CAS 10049-21-5	SODIUM PHOSPHATE MONOBASIC MONOHYDRATE	0,5-1%
CAS 7758-79-4	SODIUM PHOSPHATE DIBASIC	0,5-1%

pH 7 ± 0,1

Buffer molarity: 75 millimoles/litre



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## **FIXATION TECHNIQUE**

SAMPLE/FIXATIVE RATIO : 1/15-20 (volume)  
SAMPLE MAXIMUM THICKNESS : 1 cm

Product intended for professional users.

Ensure that the ratio "Sample volume/Fixative volume" is suitable for correct sample fixation.

The guidelines suggest: *"the volume of the ratio of fixative to tissue should be included in the procedures of collection, handling and presentation ie the volume of formaldehyde should be 15-20 times the volume of the sample".*

## **INSTRUCTIONS FOR USE**

1. Unscrew the cap and insert the sample in the container (A)
2. Tighten the cap (the formaldehyde solution is contained in the under cap tank) (B)
3. Tear off the safety seal
4. Complete the screwing of the cap so that the formaldehyde contained the under cap (B) can be released and enter the container (A) where the sample was previously introduced
5. When the operation at point 4 is completed, the formaldehyde will come down without any further operations.



## **STORAGE AND DISPOSAL**

Keep protected from light, store at room temperature in a cool and dry place.

Once used, the devices are to be considered special waste and must be disposed of according to local regulations.

Product shelf life: 5 years.

## **LABELLING**

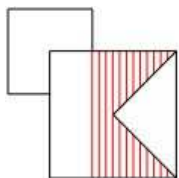
Labelling according CLP 1272/2008 Regulation

UNI EN ISO 7010 standard (Biohazard symbol)

## **CONFORMITY**

The product complies with the following Directive and Standard:

- 2017/746 UE Regulation
- UNI EN ISO 9001
- UNI CEI EN ISO 13485
- UNI CEI EN ISO 14971
- UNI CEI EN 15223-1



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## ACCESSORIES

### **FILTER FOR BIOPROTEKTOR 90**

**REF. 5078**



MANUFACTURER : KALTEK SRL  
IVD CLASS : A  
EMDN : W050301029099  
GIVD (EDMA) : 51.09.10.01  
UDI-DI : 08055510564209

#### **FEATURES**

Disposable filter for BIOPROTEKTOR90 container (cod. 4978).

Thanks to its shape and structure it allows the formaldehyde to get off the safety cap preventing, during transportation, the return of formaldehyde and consequently also of biopsy material present inside the container.

DIMENSIONS :  $\varnothing$  40 mm x 38 h  
MATERIAL : POLYPROPYLENE and POLYESTER FILAMENT

**PACKAGING:** 100 pcs

#### **STORAGE AND DISPOSAL**

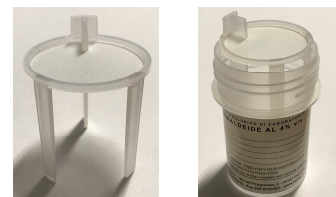
Keep protected from light, store at room temperature in a cool and dry place.

The product is incinerable and must be disposed through an authorized waste firm in compliance with national and local regulations.

#### **CONFORMITY**

The product complies with the following Directive and Standard:

- 2017/746 UE Regulation
- UNI EN ISO 9001
- UNI EN ISO 13485
- UNI CEI EN ISO 14971
- UNI EN 14254
- UNI CEI EN 15223



POLYESTER FILTER DETAIL

### **WRENCH FOR BIOPROTEKTOR**

**REF. 5070**

PLASTIC WRENCH FOR SCREW CAP  
suitable for containers BIOPROTEKTOR 90 – 150

Not subjected to CE mark.

