

# TECHNICAL SHEET

## B5300ST

### BIOPROTEKTOR 20

#### SAFETY CONTAINER

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



#### INTENDED USE

**Closed circuit** disposable container pre-filled with 8% buffered coloured Formaldehyde solution designed for the transport and storage of biological samples ensuring maximum safety for the operator who does not come into contact with the fixative.

Suitable for holding embedding cassettes (normal and micro).

Ready to use, no assembly required.

REF.	UDI-DI	CONTAINER ACTUAL CAPACITY	8% FORMALDEHYDE QUANTITY	WATER QUANTITY	CONTAINER DIMENSIONS	CONTAINER TOTAL HEIGHT (cap included)	PACKAGING
5300	08055510563196	40 ml	10 ml	10 ml	Ø 34 X h 68,5 mm	107 mm	24 pcs

#### CHARACTERISTICS

- Container (A) containing water to facilitate the detachment of the sample from the needle.
- Screw cap (B) with knurled edges to facilitate opening and closing operations, provided with a safety seal for checking the activation of the circuit.
- Sealed capsule (C), inserted inside the cap, containing 8% buffered formaldehyde with pink dye.



#### CONTENT

BUFFERED COLOURED FORMALDEHYDE 8% - (Assay % w/v 8.0 - 8.8)

pH (20°C) 6.9 - 7.1

Absorbance at 520 nm: 0,05 - 0,09

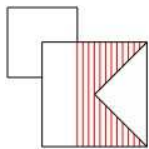
WATER

#### ACTIVATION

Apply a slight pressure on the cap to allow the 8% formaldehyde solution to enter the container by joining the water (patented system).

After activation, the sample is immersed in a 4% formaldehyde solution obtained by diluting 8% formaldehyde with water, excluding any possibility of exposure to the fixative by the operator.

Even in the case of incorrect transport (container lying on the side), the sample will remain completely immersed in the fixative and the activation system will prevent the return of the biopsy into the safety capsule.



#### **FIXATION TECHNIQUE**

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

MAXIMUM THICKNESS OF SAMPLE: 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 that is the volume of formaldehyde should be 15-20 times the volume of the sample".*

#### **MATERIALS**

The container is made exclusively of non-toxic materials free of latex and phthalates. In addition, the construction technology has allowed a reduced amount of plastic to benefit the environment.

EXTERNAL CONTAINER : POLYPROPYLENE (PP)  
UNDER-CAP : HIGH DENSITY POLYETHYLENE (HDPE)  
PLUNGER : LOW DENSITY POLYETHYLENE + MEGOL  
CAP : LOW DENSITY POLYETHYLENE  
SPRING : POM

#### **COLOR**

Container : Neutral (semi-transparent white)  
Cap : Pink

#### **STORAGE AND DISPOSAL**

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

Disposed of the product through an authorized waste firm in compliance with national and local regulations

The product is incinerable.

**SHELF LIFE:** 5 years

#### **LABELLING**

Labelling according to:

- 1272/2008 EC Regulation (CLP)
- UNI EN ISO 7010 standard (symbol Biohazard)

#### **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

