



## KLESSIDRA 30 Blue

with coloured formalin



CODE	PACKAGING
05-01V15PKFC	27 prefilled containers with 10 ml of formaldehyde 12% and 27 prefilled containers with 20 ml of buffer



In Vitro Diagnostic – Medical Device  
EMDN: W01030705  
IVD in **Classe A**, Reg. UE 2017/746

UDI-DI: 08034120277235  
Basic UDI: 080341202W01030705AJ



Manufacturer: Bio-Optica Milano S.p.A.



Disposable device

### TECHNICAL FEATURES

Code	Unit size	Container capacity	Filling volume	Container dimensions (cm)	Box dimensions (cm)
05-01V15PKFC	27 x 10 ml formaldehyde 12% container 27 x 20 ml buffer container	35 ml 55 ml	10 ml of blue formaldehyde 20 ml of buffer	Ø 3,4 x h 4,5 Ø 3,4 x h 6,7	24 x 38 x 7,2

### PRODUCT DETAILS

Klessidra 30 Blue is a special closed-circuit system that prevents the contact between formaldehyde and the user **in compliance with the European Regulation 605/2014**. It is ideal for the fixation and the transport of small histologic specimens.

The device consists of two containers in neutral PP:

- one, with the yellow lid, prefilled with a buffered solution where the biopsy can be easily released;
- one, with a special double blue lid prefilled with concentrated formaldehyde, to be screwed on the container with the biopsy.

A special double screw lid in blue PE connects the two containers.

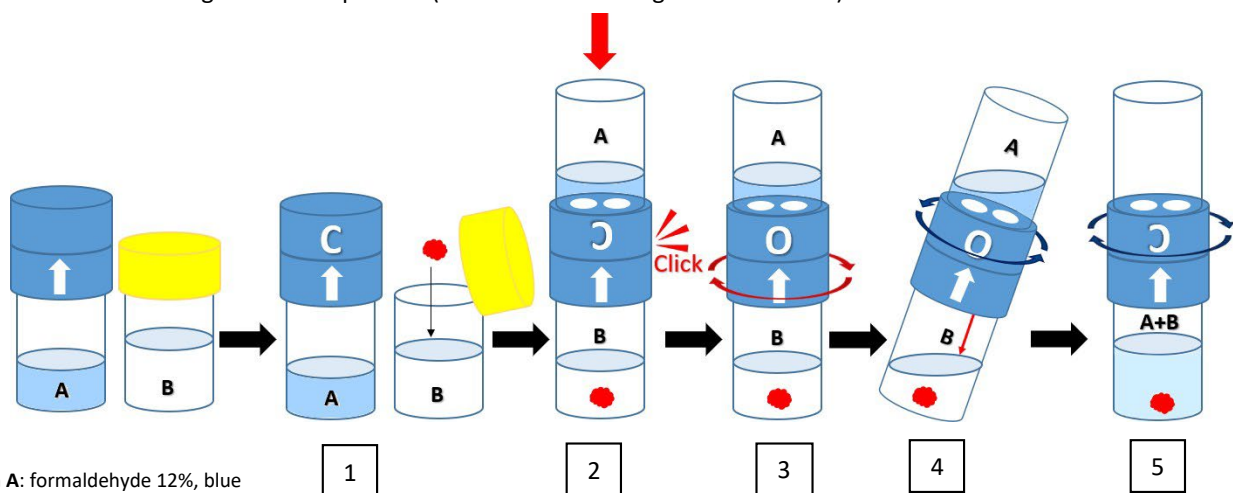
The formalin flow between the two containers is possible thanks to two holes on the double lid that are aligned after rotating the two parts of it. The seal is guaranteed by two silicon spheres for the occlusion of the holes and by the conformity with the standard **UNI EN 14254:2004**.

The device is provided by a mechanism which prevents the reflux of formalin into the previous container in order to avoid Ipfixation problems and the loss of the biopsies. The final formalin concentration is 10%. The product is latex free.

**Thanks to the presence of blue coloured formalin in the prefilled container, it is possible to easily make sure that the fixative has flowed down since at the end of the operation, the colourless buffer solution becomes blue.**

### INSTRUCTIONS FOR USE

- 1) Open the container with the yellow lid containing the buffer (solution B) and release the biopsy;
- 2) On a flat surface, connect the containers (solution A on top) and apply a slight pressure from above (red arrow) in order to get the correct alignment.
- 3) On a flat surface, screw the container prefilled with formalin (solution A) on the container with the biopsy (solution B);
- 4) Rotate the two lids in open position (until the arrow is aligned with the "O") and tilt the dispositive and let the formalin flow in the lower container;
- 5) Rotate the two lids again in close position (until the arrow is aligned with the "C").




Solution A: formaldehyde 12%, blue  
Solution B: phosphate buffer, colourless  
Solution A+B: neutral buffered formalin 10%, blue

## Technical details

Specifications	Expected aim	Product for the preparation of cyto-histological samples for optical microscopy. Safety fixation and transport with 10% neutral buffered formalin (equivalent to an aqueous solution of 4% formaldehyde).		
	Intended use	Fixative for histology.		
	Principle	<p>Interaction between formaldehyde and functional groups in tissue macromolecules (proteins and nucleic acids) occurs as follow:</p> <ul style="list-style-type: none"> <li>-The formaldehyde molecule in water gives the following equilibrium  <math>CH_2O + H_2O = CH_2(OH)_2</math> with the formation of methylene glycol.</li> <li>- Methylene glycol interacts primarily with functional groups in the side chains of proteins and with acids stabilizing the nuclear structure.</li> <li>- Formaldehyde form crosslinks between the free amino groups present in the side chains of amino acids.</li> </ul>		
	Technical specifications	pH	7,2 ± 0,2	
		Density	1,003	
		Buffer molarity	0,05 M	
	Fixation technique	Specimen / fixative ratio	1:20 (volume)	
		Specimen thickness	1 cm	
		Fixation time at room temperature	For specimens up to 5 mm 5 hours For greater thickness 1-2 days	
	Packaging	Primary container: container in neutral PP with blue screw cap in PE and container in neutral PP with yellow screw cap in PE. Secondary container: carton box, white colour. Wear, water, alcohol and solvents resistant PVC label. Scratchproof ink resistant to water and alcohol.		
Components	Formaldehyde 12% p/v	CAS: 50-00-0	CE: 200-001-8	Index: 605-001-00-5
	Methanol 0,1% v/v	CAS: 67-56-1	CE: 200-659-6	Index: 603-001-00-X
	Sodium phosphate monobasic monohydrate 0,15-0,2% p/v	CAS: 7558-80-7	CE: 231-449-2	-
	Sodium phosphate dibasic dihydrate 0,7-0,8% p/v	CAS: 10028-24-7	CE: 231-448-7	-
	Deionized water	-	-	-
Storage	Storage	Store the preparation at 15-25°C. Keep the containers tightly closed.		
	Storage temperature	15-25°C		
	Stability	After opening, it is usable until the expiry date, if correctly stored.		
	Validity	2 years		

Warning	Product classification	The product is intended for professional laboratory use for healthcare professionals. Carefully read the information on the label (danger symbols, risk and safety phrases) and always consult the safety data sheet. Do not use if the primary container is damaged. In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.
	Disposal	Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.
	Transport	It is not recommended to transport by air

### Accessories for Klessidra

CODE	DESCRIPTION	IMAGE	QUANTITY
05-900900	Accessory - shockproof plexiglass rack with 16 places for an easy transport of Klessidra		2 pcs

### Literature

Lott R, Tunnicliffe J, Sheppard E, et al.; National Society for Histotechnology HistoQIP Committee. *Pre-Microscopic Examination Specimen Handling Guidelines in the Surgical Pathology Laboratory*. Northfield, IL: College of American Pathologists;2014

REVISION n°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022
002	Product name update	22/07/2024