



BIO FIX



CODE	UNIT SIZE
05-X200	4 x 200 ml



In-vitro diagnostic medical device
EMDN: W01030705
IVD in **Class A**, Reg. UE 2017/746



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

Basic UDI: 080339762W01030705X2
UDI-DI: 08033976235079

Spray fixative for vaginal cytology.

FIXATION TECHNIQUE

- 1) Spray evenly on the smear (3-4 times). Wait for 7 minutes, until the protective film is formed.
- 2) The formation of a resistant and soluble film allows to best preserve the cellular material until staining.
- 3) The fixed smear can be directly stained. Nevertheless, removal of the waxy film in distilled water (1-2 minutes) is recommended.

Technical features

Method specifications	Expected aim	Product for the preparation of cyto-histological samples for optical microscopy. Spray fixative for vaginal cytology.		
Packaging	Primary container	White PVC bottle with spray and protective cap. Useful capacity 200 ml		
	Label	Serigraphy resistant to water, alcohol and solvents. Wear, water, alcohol and solvents resistant PVC label. Scratchproof ink resistant to water and alcohol.		
	Secondary container	Carton box.		
Components	Ethanol 55%	CAS: 64-17-5	CE: 200-578-5	Index: 002-00-5
	Isopropanol 30%	CAS: 67-63-0	CE: 200-661-7	Index: 603-117-00-0
	Hydrosoluble polymers 5 %	-	-	-
	Deionized water 10%	-	-	-
Storage	Storage temperature	Store the preparation at room temperature. Keep the containers tightly closed.		
	Stability	After the first opening, the product is reusable until the expiry date, if correctly stored.		
	Validity	5 years		
Warning	Product classification	<p>The product is intended for professional laboratory use for healthcare professionals.</p> <p>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.</p> <p>In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.</p>		
	Disposal	Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.		

REVISION n°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022