



BIOWAX PARAFFIN



CODE	SIZE	PACKAGING	UDI-DI
08-7960	1 kg	8 x 1 kg	08034120278355
450012	3,8 kg	3 x 3,8 kg	08034120278706



In vitro Diagnostic – Medical device
EMDN: W01030799
IVD Class A, Reg. UE 2017/746
Basic UDI: 080341202W01030799BM



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

Date of issue: 11/06/2024
Rev. 003

Mixture of pure paraffin (aliphatic hydrocarbons) and additive polymers (concentration: 0.3%) for histological samples embeddings.

The products do not contain DMSO.

PRODUCTIVE PROCESS AND QUALITY CONTROL

The manufacturing process concerning the Bio Plast waxes is managed and controlled by a company managerial system which is completely computerized. The laboratory staff places the production formula on the system when they make a sales order and generates a new production lot.

This formula has been filed away and is available in the managerial informatics system of the company and it includes the list of the raw materials, essential for the production of the final product and the required amount.

Based on the production formula assigned by the laboratory, the authorized production staff start the production: the exact amount of product is automatically taken from the tank, in order to follow the typology and the right amount marked by the pre-assigned formula.

The computerized system is constantly controlling the parameters and alerts in the event of an irregularity.

Operation	Operation's description	Responsibility	Process parameters –Productive line	Registration
1	Assignment of the production formula, concerning the item to produce, with the list of the components and related percentages: <ul style="list-style-type: none"> • Paraffin (in precise %) • Plasticizer additive (in precise %). 	Laboratory	Informatics' Company System.	/
2	Melting and blending of the raw materials: production starting following the assigned formula. The installation automatically draws out the constituent stated in the production formula given by the laboratory, in the exact amount and by the storage tank, in which you find the components to use (always automatically).	Production operators	Melter production line and company informatics' system. Parameters reported in the notes of the production in the company automated system.	/
3	Quality check on taken sample.	Laboratory/ Quality check	Check specifics reported in the informatics' system.	CoA
4	Solidification of the paraffins: the manufacturing is automatically run by the production installation.	Automatic	Drop line production and managing company system, following the parameters reported in the notes of the production, concerning the assigned production formula.	/
5	Packing	Production staff	Packing specifics	/
6	Check on the packing.	Production staff- Laboratory	/	/

Date of issue: 11/06/2024

Rev. 003

Technical data

Paraffin technical data	Composition	Mixture of pure paraffins and additive polymers
	Oil percentage (ASTM D721)	< 0.5%
	Melting point	56 – 58 °C
	Shape	Drops
	Colour	White
	Use	Routine high quality qualità
	Needle penetration (25°C) (ASTM D1321)	21 +/- 3 dmm
	Purity	Triple filtration during the manufacturing process
	Physical state	Solido
Packaging	Primary container	Plastic bag
	Label	Paper label
	Secondary container	Plastic box
Storage	Storing condition	Store the paraffin at maximum temperature 38°C. At temperature higher than 38°C paraffin drops begin to aggregate. Keep the bags closed.
	Temperature storage	< 38°C
	Stability	After the first opening, the paraffin is valid until the expiry date, if correctly stored.
	Validity	3 years
	Method of use	At a temperature higher than 63°C paraffins lose their plastic properties. This fact may produce a black precipitate on the bottom of processor container and embedding station and induce cracks in the blocks and problems during the cutting. Always check the temperatures of the paraffins baths in the processing system and in the inclusion station. During the embedding passage, set the cold plate temperature up about - 5°C. Too low temperatures (- 15 / - 20°C) cause thermal shock and produce cracks in the blocks, making difficult cutting.
Warning and precautions	Classification of the product	The product is intended for professional laboratory use for healthcare professionals. The product doesn't contain DMSO and it is not chemically dangerous. Always consult the safety data sheet.
	Disposal	After use with tissue processor/embedding station, dispose as special waste and keep it to specialized and authorized company, in conformity with local legislation. If not used, dispose as written in safety datasheet

Date of issue: 11/06/2024

Rev. 003

	Recommendations	In the event of a serious accident, we recommend that you immediately inform Bio-Optica Milano S.p.A. and the competent authorities.
--	-----------------	--

REVISION N°	REASON	REVISION DATE
001	First issue	22/09/2022
002	Entering technical specifications	03/05/2023
003	Entering new code	11/06/2024

Date of issue: 11/06/2024
Rev. 003