ALCHIMIA

GLYO•ON

500 ML SINGLE USE PRODUCT

SOLUTION FOR CRYOPRESERVATION AND GLYCEROLIZATION OF HUMAN TISSUES AND CELLS INTENDED FOR TRANSPLANTATION

CRYOPRESERVATION / GLYCEROLIZATION

	GLYO•ON
Ingredients	Action
100% glycerol	tissue and cell protection during storage at cryogenic temperatures/glycerolization
Physical parameters:	
Aspect	sterile, trasparent and colorless liquid
Purity	≥ 99.5% (tested by GC)
Microbiological parameters:	
Endotoxins	tested according to EP and USP < 0.0375 EU/ml < 20 EU/device according to USP
Mycoplasmas	absent, tested according to EP and USP
Sterilization	moist heat according to EN 556-1 and EN ISO 17665-1
Packaging	tight-fitted class I amber glass vial with butyl rubber closure in a sterile double pouch
Volume	500 ml
Storage temperature	room temperature
Expiry date	36 months
Intended use	cryopreservation/glycerolization of human tissues and cells intended for transplantation
Class	medical device
CND Code	V9099
MD registration number	479894/R
Medical device class	IIa
CE mark	CE 0546

GLYO•ON is glycerol with purity higher than 99.5%, which is certified for use with human tissues and cells intended for transplantation. Product is sterile, apyrogenic and mycoplasma tested according to the current Pharmacopoeias (EP and USP). It is packaged in sterile double pouch to meet GMP requirements.

Ref.: GLY 002

Contents:

- 1 vial of 500 ml GLYO•ON in sterile double pouch
- 4 labels for product traceability
- 1 package insert

GS1-128 barcode

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