

# GLYO.ON

500 ML SINGLE USE PRODUCT

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

## CRYOPRESERVATION / GLYCEROLIZATION

GLYO.ON	
<b>Ingredient</b>	Action
<b>100% glycerol</b>	tissue and cell protection during storage at cryogenic temperatures/glycerolization
<b>Physical parameters:</b>	
<b>Aspect</b>	sterile, transparent and colorless liquid
<b>Purity</b>	> 99.5% (tested by GC)
<b>Microbiological parameters:</b>	
<b>Endotoxins</b>	tested according to EP and USP < 0.0375 EU/ml < 20 EU/device according to USP
<b>Mycoplasmas</b>	absent, tested according to EP and USP
<b>Sterilization</b>	moist heat according to EN 556-1 and EN ISO 17665-1
<b>Packaging</b>	tight-fitted class I amber glass vial with butyl rubber closure in a sterile double pouch
<b>Volume</b>	500 ml
<b>Storage temperature</b>	room temperature
<b>Expiry date</b>	36 months
<b>Intended use</b>	cryopreservation/glycerolization of human tissues and cells intended for transplantation
<b>Class</b>	medical device
<b>CND Code</b>	V9099
<b>MD registration number</b>	479894/R
<b>Medical device class</b>	Ila
<b>CE mark</b>	CE 0477

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**

**ALCHIMIA**

Viale Austria, 14  
35020 Ponte S.Nicolò (PD)  
Italy

VAT IT 00063370282

Phone +39 049 8962074 / 64  
Fax +39 049 8962071

www.alchimiasrl.com  
info@alchimiasrl.com