

# RS-OIL 2000

HIGH PURITY STERILE SILICONE OIL, 2000 cSt, 15 ML FOR INTRAOCULAR TAMPONADE

## SILICONE OIL

	RS-OIL 2000
<b>Ingredient</b>	100% silicone oil, obtained from the mixture of long and short molecular chains (100% polydimethylsiloxane)
<b>Viscosity (25°C)</b>	1900 - 2100 cSt
<b>Specific gravity (25°C)</b>	0.967 - 0.975
<b>Refractive index (25°C)</b>	1.40
<b>Acidity index</b>	≤ 0.15 ml NaOH 0.01 N
<b>Heavy metals</b>	≤ 5 ppm
<b>Phenolic compounds</b>	≤ 0.20 (250 - 270 nm)
<b>Volatility (10g/24h/150°C)</b>	≤ 0.10 %w/w
<b>Bacterial endotoxins</b>	< 0.2 EU/ml
<b>Cytotoxicity Test</b>	Non-cytotoxic according to ISO 10993-5, direct contact test performed on two cell lines: - retinal pigment epithelial cells (ARPE-19) - mouse fibroblasts cells (BALB 3T3 clone A31)
<b>Form</b>	sterile fluid
<b>Volume</b>	15 ml
<b>Packaging</b>	vial in medical pouch
<b>Sterilization</b>	moist heat according to EN ISO 17665-1
<b>Storage temperature</b>	room temperature
<b>Expiry date</b>	36 months
<b>Intended use</b>	intraocular tamponade during vitreoretinal surgery
<b>Class</b>	medical device
<b>GMDN code</b>	P 45125
<b>CND code</b>	Q 02030202
<b>MD registration number</b>	970326/R
<b>Medical device class</b>	IIb
<b>CE mark</b>	CE 0477

RS-OIL is highly purified silicone oil (100% pure polydimethylsiloxane), 2000 cSt, 15 ml, sterile and apyrogenic, packaged in vial, intended for long-term replacement of the vitreous humour extracted during vitreoretinal surgery. Product warrants a stable tamponade over the time and reduced incidence of complications.

**Ref.:** RSO 012-00

### Contents:

- ▶ 1 RS-OIL 2000 vial (100% high purity, sterile silicone oil 2000 cSt, 15 ml)
- ▶ 3 labels for product traceability
- ▶ 1 package insert

**GS1-128 barcode**

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