

# QUALITY ASSURANCE CERTIFICATE



Light, highly purified, paraffin oil, to be used as an overlay for culturing gametes and zygotes.

Containing: 300 mL

Catalogue no: NO-300

Batch:  
**300NOVD21**

Production date:  
**21 April, 2015**

Expiry date:  
**20 April, 2017**

We certify that this product was manufactured according to set directives for medical devices. The quality of this particular batch was tested and evaluated objectively by stringent, quality control procedures.

## Quality Control procedures:

## Accepted values:

## Test results:

### **Physical analyses**

Density (d 20°C / 20°C, g/mL)

0.82-0.88

0.85

### **Sterility and toxin analyses**

Microbiological growth control

No growth

Comply

Endotoxins, quantitative LAL assay (EU/mL)

< 0.100

<0.005

### **Biological analyses**

Mouse Embryo Assay (% development to blastocyst stage at day 5)

≥80

Comply

Human sperm survival after 18 hrs

≥85

Comply

### **Peroxide analyses**

Peroxide level (mEq/kg)

<0.02

0.0012

Date of release: 12 June, 2015

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C.E.O.

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