

# QUALITY ASSURANCE CERTIFICATE



NidOil™

An oil overlay for use during ICSI or gamete and embryo culture, inside or outside the incubator.

Containing: 4x100 mL

Catalogue no: NO-400K

Batch:  
**100NOYI04**

Production date:  
**04 September, 2018**

Expiry date:  
**03 September, 2020**

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:

### **Physical analyses**

Density (d 20°C / 20°C, g/mL)

### Accepted values:

0.82-0.88

### Test results:

0.846

### **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

0.0018

Date of release: 14 November, 2018

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C.E.O.

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