

# QUALITY ASSURANCE CERTIFICATE



NidOil™

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

Containing: 100 mL

Catalogue no: NO-100

Batch:  
**100NOWJ24-2**

Production date:  
**24 October, 2016**

Expiry date:  
**23 October, 2018**

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:

|   | <u>Accepted values:</u> | <u>Test results:</u> |
|---|-------------------------|----------------------|
| <b>Physical analyses</b>  |                         |                      |
| Density (d 20°C / 20°C, g/mL)                                   | 0.82-0.88               | 0.849                |
| <b>Sterility and toxin analyses</b>                             |                         |                      |
| Microbiological growth control                                  | No growth               | Comply               |
| Endotoxins, quantitative LAL assay (EU/mL)                      | < 0.100                 | < 0.005              |
| <b>Biological analyses</b>                                      |                         |                      |
| Mouse Embryo Assay (% development to blastocyst stage at day 5) | ≥80                     | Comply               |
| Human sperm survival after 18 hrs                               | ≥85                     | Comply               |
| <b>Peroxide analyses</b>  |                         |                      |
| Peroxide level (mEq/kg)   | <0.02                   | 0.0012               |

Date of release: 06 December, 2016

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C.E.O.

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