

QUALITY ASSURANCE CERTIFICATE



NidOil™

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

Containing: 300 mL

Catalogue no: NO-300

Batch:
300NOVC31

Production date:
31 March, 2015

Expiry date:
30 March, 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: 07 May, 2015

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C.E.O.

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