

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:
300NOWE31-2

Production date:
31 May, 2016

Expiry date:
30 May, 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:

Accepted values:

Test results:

Physical analyses

Density (d 20°C / 20°C, g/mL)

0.82-0.88

0.849

Sterility and toxin analyses

Microbiological growth control

No growth

Comply

Endotoxins, quantitative LAL assay (EU/mL)

< 0.100

<0. 05

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

0.008

Date of release: 01 July, 2016

This document is electronically generated and does not bear a signature.

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C.E.O.

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