

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:
300NOWC15-1

Production date:
15 March, 2016

Expiry date:
14 March, 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.

<u>Quality Control procedures:</u>	<u>Accepted values:</u>	<u>Test results:</u>
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	<0.1
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	0.0028

Date of release: 29 March, 2016

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C.E.O.

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