

# 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:  
**100NOZD09**

Production date:  
**09 April, 2019**

Expiry date:  
**08 April, 2021**

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	<0.0029

Date of release: 9 May 2019

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C.E.O.

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