

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:
100NOZA21-1

Production date:
21 January, 2019

Expiry date:
20 January, 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>
Physical analyses		
Density (d 20°C / 20°C, g/mL)	0.82-0.88	0.848
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	0.0029

Date of release: 17 April, 2019

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

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C.E.O.

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