

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:
100NOZC26-1

Production date:
26 March, 2019

Expiry date:
25 March, 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 | 0.849 |
| 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 | <0.0033 |

Date of release: 09 May 2019

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

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C.E.O.

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