

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:
100NOXL05-1

Production date:
05 December, 2017

Expiry date:
04 December, 2019

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:

Physical analyses

Density (d 20°C / 20°C, g/mL)

Accepted values:

0.82-0.88

Test results:

0.0852

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

0.0027

Date of release: 04 January, 2018

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

Paul V. Holmes, MSc, PhD, DrMedSc
C.E.O.

Marina Danilova
Quality Assurance Coordinator

Nidacon International AB
Flöjelbergsgatan 16B, SE-431 37 Mölndal, Sweden
Tel:+46-31-703 06 30 Fax:+46-31-40 54 15
E-mail: contact@nidacon.com Web: www.nidacon.com