

QUALITY ASSURANCE CERTIFICATE



NidOil™

Light, highly purified, paraffin oil, to be used as an overlay for culturing gametes and zygotes.

Containing: 100 mL

Catalogue no: NO-100

Batch:
100NOXE10

Production date:
10 May, 2017

Expiry date:
09 May, 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:

	<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	0.0028

Date of release: 02 June, 2017

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