

# 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:  
**100NOXL07**

Production date:  
**07 December, 2017**

Expiry date:  
**06 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:

	<u>Accepted values:</u>	<u>Test results:</u>
<b>Physical analyses</b>		
Density (d 20°C / 20°C, g/mL)	0.82-0.88	0.0851
<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	0.0035

Date of release: 04 January, 2018

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**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](mailto:contact@nidacon.com) Web: [www.nidacon.com](http://www.nidacon.com)