QUALITY ASSURANCE CERTIFICATE



Nid0il[™]

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

Containing: 300 mL Catalogue no: NO-300

 Batch:
 Production date:
 Expiry date:

 300NOWE31-3
 31 May, 2016
 30 May, 2018

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:	Accepted values:	Test results:
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	<0.05
Biological analyses		
Mouse Embryo Assay (% development to	<u>></u> 80	Comply
blastocyst stage at day 5)		
Human sperm survival after 18 hrs	<u>></u> 85	Comply
Peroxide analyses		
Peroxide level (mEq/kg)	<0.02	0.006

Date of release: 01 July, 2016

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

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