

# QUALITY ASSURANCE CERTIFICATE



PureSperm® 100

Colloidal stock suspension optimised for discontinuous density gradient separation of human sperm.

Containing: 100 mL

Catalogue no: PS100-100

Batch:  
**100PS100XB02**

Production date:  
**02 February, 2017**

Expiry date:  
**01 February, 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.

<u>Quality Control procedures:</u>	<u>Accepted values:</u>	<u>Test results:</u>
<b>Physical analyses:</b>		
<i>pH at room temperature in air</i>	7.4-7.8	Comply
<i>Osmolality (mOsm)</i>	300-310	Comply
<b>Sterility and toxin analyses:</b>		
<i>Microbiological growth control</i>	No growth	Comply
<i>Endotoxin transfer during treatment, quantitative LAL assay (EU/mL)</i>	<1.0	Comply
<b>Biological analyses:</b>		
<i>Human sperm survival after 18 hrs</i>	>70 %	Comply

Date of release: 16 March, 2017

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

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C.E.O.

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