

# QUALITY ASSURANCE CERTIFICATE



PureSperm<sup>®</sup> 100

Stable colloid/isotonic salt solution for preparation of density gradient used to separate human sperm.

Containing: 100 mL

Catalogue no: PS100-100

Batch:  
**100PS100YB21**

Production date:  
**21 February, 2018**

Expiry date:  
**20 February, 2020**

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

Date of release: 05 June, 2018

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

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C.E.O.

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