

QUALITY ASSURANCE CERTIFICATE



PureSperm™ 80

For separation of human sperm with density centrifugation.

Containing: 100 mL

Catalogue no: PS80-100

Batch:
100PS80GC23

Production date:
23 March 2026

Expiry date:
22 March 2028

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>
Physical analyses:		
<i>pH at room temperature in air</i>	7.4-7.8	Comply
<i>Osmolality (mOsm)</i>	300-310	Comply
Sterility and toxin analyses:		
<i>Microbiological growth control</i>	No growth	Comply
<i>Endotoxins, quantitative LAL assay (EU/mL)</i>	< 1.00	Comply
Biological analyses:		
<i>Human sperm survival after 18 hrs</i>	>70 %	Comply

Date of release: 09 April 2026

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

Marina Danilova,
Quality Assurance Coordinator

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