

# QUALITY ASSURANCE CERTIFICATE



PureSperm® 100

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

Containing: 100 mL

Catalogue no: PS100-100

Batch:  
**100PS100XH28**

Production date:  
**28 August, 2017**

Expiry date:  
**27 August, 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:**

**Accepted values:**

**Test results:**

**Physical analyses:**

*pH at room temperature in air*

*7.4-7.8*

Comply

*Osmolality (mOsm)*

*300-310*

Comply

**Sterility and toxin analyses:**

*Microbiological growth control*

*No growth*

Comply

*Endotoxin transfer during treatment,  
quantitative LAL assay (EU/mL)*

*<1.0*

Comply

**Biological analyses:**

*Human sperm survival after 18 hrs*

*>70 %*

Comply

*Date of release: 02 November, 2017*

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

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C.E.O.

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