

# QUALITY ASSURANCE CERTIFICATE



PureSperm<sup>®</sup> 100

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

Containing: 250 mL

Catalogue no: PS100-250

Batch:  
**250PS100VH18**

Production date:  
**18 August, 2015**

Expiry date:  
**17 August, 2017**

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)*

*< 1.00*

*Comply*

***Biological analyses:***

*Human sperm survival after 18 hrs*

*>70 %*

*Comply*

*Date of release: 05 October, 2015*

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

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C.E.O.

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