

# QUALITY ASSURANCE CERTIFICATE

PureSperm<sup>®</sup> Wash

Optimised for washing the sperm pellet recovered from a PureSperm<sup>®</sup> density gradient separation, for use in the swim-up method and extending semen or sperm pellet for use in IUI.

Containing: 20 mL

Catalogue no: PSW-020

Batch:  
**020PSWWG05**

Production date:  
**05 July, 2016**

Expiry date:  
**04 July, 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*

*7.3-8.5*

*Comply*

*Osmolality (mOsm)*

*290-300*

*Comply*

***Sterility and toxin analyses:***

*Microbiological growth control*

*No growth*

*Comply*

*Endotoxins, quantitative LAL assay  
(EU/mL)*

*< 1.00*

*Comply*

***Biological analyses:***

*Human sperm survival after 18 hrs*

*>70 %*

*Comply*

*Date of release: 12 August, 2016*

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

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C.E.O.

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