

# 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: 100 mL

Catalogue no: PSW-100

Batch:  
**100PSWVB16**

Production date:  
**16 February, 2015**

Expiry date:  
**15 February, 2016**

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  
Osmolality (mOsm)

7.3-8.5  
290-300

Comply  
Comply

#### **Sterility and toxin analyses:**

Microbiological growth control  
Endotoxins, quantitative LAL assay  
(EU/mL)

No growth  
< 1.00

Comply  
Comply

#### **Biological analyses:**

Human sperm survival after 18 hrs

>70 %

Comply

Date of release: 22 April, 2015

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