

# QUALITY ASSURANCE CERTIFICATE



## PureSperm<sup>®</sup> Wash

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

Containing: 100 mL

Catalogue no: PSW-100

Batch:  
**100PSWYJ11**

Production date:  
**11 October, 2018**

Expiry date:  
**10 October, 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*

7.3-8.5

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: 14 December, 2018

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