

# 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:  
**100PSWYL19**

Production date:  
**19 December, 2018**

Expiry date:  
**18 December, 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: 08 February, 2019

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