

# QUALITY ASSURANCE CERTIFICATE



PureSperm® 100

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

Containing: 250 mL

Catalogue no: PS100-250

4x250mL

PS100-1000K

Batch:  
**250PS100WI20**

Production date:  
**20 September, 2016**

Expiry date:  
**19 September, 2018**

We certify that this product was manufactured with pharmaceutical quality (ISO 13485) according to the requirements in Annex I in the MDD 93/42/EEC directive. 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: 25 October, 2016

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C.E.O.

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