

QUALITY ASSURANCE CERTIFICATE



PureSperm® Buffer

Optimised for the dilution of PureSperm® 100 in the preparation of density gradients.

Containing: 100 mL

Catalogue no: PSB-100

Batch:
100PSBUK24

Production date:
24 November 2014

Expiry date:
23 November, 2016

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.

<u>Quality Control procedures:</u>	<u>Accepted values:</u>	<u>Test results:</u>
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
Endotoxins, quantitative LAL assay (EU/mL)	< 1.00	Comply
Biological analyses:		
Human sperm survival after 18 hrs	>70 %	Comply

Date of release: 23 December, 2014

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C.E.O.

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