

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: 100PSBWA26 **Production date:** 26 January, 2016 **Expiry date:** 25 January, 2018

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.

<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: 01 March, 2016

This document is electronically generated and does not bear a signature.

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C.E.O.

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