

# QUALITY ASSURANCE CERTIFICATE

PureSperm<sup>®</sup> Buffer

Optimised for the dilution of PureSperm<sup>®</sup> 100 in the preparation of density gradients.

Containing: 100 mL

Catalogue no: PSB-100

Batch:  
**100PSBVI10**

Production date:  
**10 September, 2015**

Expiry date:  
**09 September, 2017**

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>
<b>Physical analyses:</b>		
pH at room temperature in air	7.4-7.8	Comply
Osmolality (mOsm)	300-310	Comply
<b>Sterility and toxin analyses:</b>		
Microbiological growth control	No growth	Comply
Endotoxins, quantitative LAL assay (EU/mL)	< 1.00	Comply
<b>Biological analyses:</b>		
Human sperm survival after 18 hrs	>70 %	Comply

Date of release: 27 October, 2015

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

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C.E.O.

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