

QUALITY ASSURANCE CERTIFICATE



PureSperm® 40/80

For preparation of density gradients used to separate human sperm.

Containing: 2 x 20 mL

Catalogue no: PSK-020

Batch: 020PS40WA12 020PS80WA13	Production date: 12 January, 2016 13 January, 2016	Expiry date: 11 January, 2018 12 January, 2018
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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>	
		<i>PureSperm® 40</i>	<i>PureSperm® 80</i>
Physical analyses:			
<i>pH at room temperature and in air</i>	7.4–7.8	Comply	Comply
<i>Osmolality (mOsm)</i>	300-310	Comply	Comply
Sterility and toxin analyses:			
<i>Microbiological growth control</i>	No growth	Comply	Comply
<i>Endotoxins, transfer during treatment, quantitative LAL assay (EU/mL)</i>	< 1.00	Comply	Comply
Biological analyses:			
<i>Sperm survival 18 hrs after density-gradient preparation</i>	>70%	Comply	Comply

Date of release: 08 February, 2016

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

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C.E.O.

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