

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:

020PS40WD07

020PS80WD07

Production date:

07 April, 2016

07 April, 2016

Expiry date:

06 April, 2018

06 April, 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.

Quality Control procedures:

Accepted values

Test results

		<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: 20 May, 2016

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

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C.E.O.

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