

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:	Production date:	Expiry date:
020PS40VD15	15 April, 2015	14 April, 2017
020PS80VD15	15 April, 2015	14 April, 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>	
		<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: 06 June, 2015

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

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C.E.O.

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