

QUALITY ASSURANCE CERTIFICATE



PureSperm® 80

For preparation of density gradients used to separate human sperm.

Containing: 100 mL

Catalogue no: PS80-100

Batch:
100PS80T104

Production date:
04 September, 2013

Expiry date:
03 September, 2015

We certify that this product was manufactured with pharmaceutical quality (ISO 13485) according to the requirements in Annex I in the MDD 93/42/EEC directive. 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 transfer during treatment, quantitative LAL assay (EU/mL)	< 1.00	Comply
Biological analyses:		
Human sperm survival after 18 hrs	>70 %	Comply

Date of release: 13 November, 2013

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

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C.E.O.

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