

QUALITY ASSURANCE CERTIFICATE

PureSperm® SpeediKit

A complete kit for preparing human sperm prior to intra-uterine insemination, using single layer centrifugation.

Containing: 10 x 4 mL PureSperm® Unilayer
10 x 6 mL PureSperm Wash™

Catalogue no: PSSK-010

Batch:
PSSKPSULWD05
PSSKPSWWD04

Production date:
05 April, 2016
04 April, 2016

Expiry date:
04 April, 2017
03 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.

Quality Control procedures:

Accepted values

Test results

	PureSperm® UniLayer	PureSperm® Wash	PureSperm® Unilayer	PureSperm® Wash
Physical analyses:				
<i>pH at room temperature and in air</i>	7.4–7.8	7.3–8.5	Comply	Comply
<i>Osmolality (mOsm)</i>	300-330	290-300	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 preparation</i>	>70%		Comply	Comply

Date of release: 22 April, 2016

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C.E.O

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