

QUALITY ASSURANCE CERTIFICATE

PureSperm[®] Wash

Optimised for washing the sperm pellet recovered from a PureSperm[®] density gradient separation, for use in the swim-up method and extending semen or sperm pellet for use in IUI.

Containing: 100 mL

Catalogue no: PSW-100

Batch:
100PSWWC02

Production date:
02 March, 2016

Expiry date:
01 March, 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:

Physical analyses:

pH at room temperature in air

7.3-8.5

Comply

Osmolality (mOsm)

290-300

Comply

Sterility and toxin analyses:

Microbiological growth control

No growth

Comply

Endotoxins, quantitative LAL assay
(EU/mL)

< 1.00

Comply

Biological analyses:

Human sperm survival after 18 hrs

>70 %

Comply

Date of release: 28 April, 2016

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

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C.E.O.

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