

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: 20 mL

Catalogue no: PSW-020

Batch:
020PSWVJ13

Production date:
13 October, 2015

Expiry date:
12 October, 2016

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: 09 November, 2015

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Paul V. Holmes, MSc, PhD, DrMedSc
C.E.O.

Marina Danilova,
Quality Assurance Coordinator

Nidacon International AB
Flöjelbergsgatan 16B, SE-431 37 Mölndal, Sweden
Tel:+46-31-703 06 30 Fax:+46-31-40 54-15
E-mail: contact@nidacon.com Web: www.nidacon.com