

QUALITY ASSURANCE CERTIFICATE



PureSperm® Wash

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

Containing: 100 mL

Catalogue no: PSW-100

Batch:
100PSWZA14

Production date:
14 January, 2019

Expiry date:
13 January, 2020

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 March, 2019

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

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