

QUALITY ASSURANCE CERTIFICATE



PureSperm[®] 100

Stable colloid/isotonic salt solution for preparation of density gradient used to separate human sperm.

Containing: 4x250mL

Catalogue no: PS100-1000K

Batch:
250PS100YE07

Production date:
07 May, 2018

Expiry date:
06 May, 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

7.4-7.8

Comply

Osmolality (mOsm)

300-310

Comply

Sterility and toxin analyses:

Microbiological growth control

No growth

Comply

*Endotoxin transfer during treatment,
quantitative LAL assay (EU/mL)*

< 1.00

Comply

Biological analyses:

Human sperm survival after 18 hrs

>70 %

Comply

Date of release: 02 July, 2018

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