

QUALITY ASSURANCE CERTIFICATE



PureSperm[®] 100

Colloidal stock suspension optimised for discontinuous density gradient separation of human sperm.

Containing: 250 mL

Catalogue no: PS100-250

Batch:
250PS100UE13

Production date:
13 May, 2014

Expiry date:
12 May, 2016

We certify that this product was manufactured with pharmaceutical quality (ISO 13485) according to the requirements in Annex I in the MDD 93/42/EEC directive. 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: 26 June, 2014.

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