

# QUALITY ASSURANCE CERTIFICATE



PureSperm® 100

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

Containing: 250 mL

Catalogue no: PS100-250

Batch:  
**250PS100ZE13**

Production date:  
**13 May, 2019**

Expiry date:  
**12 May, 2021**

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  
Osmolality (mOsm)

7.4-7.8  
300-310

Comply  
Comply

**Sterility and toxin analyses:**

Microbiological growth control  
Endotoxin transfer during treatment,  
quantitative LAL assay (EU/mL)

No growth  
< 1.00

Comply  
Comply

**Biological analyses:**

Human sperm survival after 18 hrs

>70 %

Comply

Date of release: July 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](mailto:contact@nidacon.com) Web: [www.nidacon.com](http://www.nidacon.com)