

# QUALITY ASSURANCE CERTIFICATE



PureSperm<sup>®</sup> 40

For preparation of density gradients used to separate human sperm.

Containing: 100 mL

Catalogue no: PS40-100

Batch:  
**100PS40VC10**

Production date:  
**10 March, 2015**

Expiry date:  
**09 March, 2017**

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

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

< 1.00

Comply

**Biological analyses:**

*Human sperm survival after 18 hrs*

>70 %

Comply

Date of release: 27 April, 2015

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)