

# QUALITY ASSURANCE CERTIFICATE



## PureSperm<sup>®</sup> Wash

for washing the sperm pellet recovered from a PureSperm<sup>®</sup> 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:  
**100PSWXK06**

Production date:  
**06 November, 2017**

Expiry date:  
**05 November, 2018**

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: 03 January, 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](mailto:contact@nidacon.com) Web: [www.nidacon.com](http://www.nidacon.com)