

# QUALITY ASSURANCE CERTIFICATE

## PureSperm<sup>®</sup> Wash

Optimised for washing the sperm pellet recovered from a PureSperm<sup>®</sup> density gradient separation, for use in the swim-up method and extending semen or sperm pellet for use in IUI.

Containing: 100 mL

Catalogue no: PSW-100

Batch:  
**100PSWWF01**

Production date:  
**01 June, 2016**

Expiry date:  
**31 May, 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  
Osmolality (mOsm)

7.3-8.5  
290-300

Comply  
Comply

**Sterility and toxin analyses:**

Microbiological growth control  
Endotoxins, quantitative LAL assay  
(EU/mL)

No growth  
< 1.00

Comply  
Comply

**Biological analyses:**

Human sperm survival after 18 hrs

>70 %

Comply

Date of release: 04 August, 2016

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**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)