QUALITY ASSURANCE CERTIFICATE



Sperm VitalStain™

Optimised one-step staining technique for assessment of sperm vitality, one of the basic tools used in semen analysis. The technique is based on the principle that dead cells will take up the red colour of eosin stain. Nigrosin is used as a counter stain to facilitate visualization of the otherwise unstained sperm.

Containing: 2 x 10 mL Catalogue no: SVS-010

Batch: Production date: Expiry date:

010SVSXI14 14 September, 2017 13 September, 2019

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:	<u>Accepted values:</u>	<u>Test results:</u>
Physical analyses:		
pH at room temperature in air	7.3-9.5	Comply
Biological analyses:		
Batch to batch functional variation	<5 %	Comply

Date of release: 26 October, 2017

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: <u>contact@nidacon.com</u> Web: www.nidacon.com

Dok: SVSDDA10-3 Ver: 2 Datum: 2015-02-02