

QUALITY ASSURANCE CERTIFICATE

SpermCatch™

Salt solution including hyaluronate, optimised for modulating sperm motility prior to ICSI.

Containing: 6 x 100 µL

Catalogue no: SC-100

Batch:
100SCVA07

Production date:
07 January, 2015

Expiry date:
06 January, 2016

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

7.0-8.5

Comply

Osmolality (mOsm)

290-320

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

>50 %

Comply

Date of release: 16 March, 2015

This document is electronically generated and does not bear a signature.

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C.E.O.

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