

# QUALITY ASSURANCE CERTIFICATE



PureSperm<sup>®</sup> 80

For separation of human sperm with density centrifugation.

Containing: 100 mL

Catalogue no: PS80-100

Batch:  
**100PS80ZE27**

Production date:  
**27 May, 2019**

Expiry date:  
**26 May, 2021**

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: 11 July 2019

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

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