

CERTIFICATE OF ANALYSIS

SparMED Aps
Toppevadvej 34-38, DK-3660
Stenlose, Denmark



EMBRYOTECH™
laboratories

ELI accession number: E5087-0713SPAR

Test Date: 07-02-2013

Reference number: OOPW-HD10, OOPW-ST10,
OOPW-CT01, OOPW-IC10,
OOPW-TF10, OOPW-CW10,
OOPW-FW04

Lot number: 07302

Description of test article(s): Oosafe® IVF Tested Plasticware

Assay system requested by customer: Endotoxin titer and interference screening using the Gel-Clot method.

LAL lot number: E4102L

Sensitivity (λ) = 0.03 EU/mL

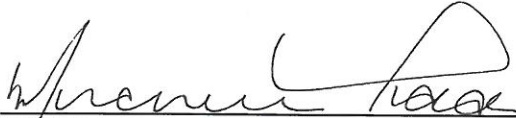
CSE lot number: EX11872

LRW lot number: 99732170

Control Standard Series			Test Sample Dilutions	NPC		PPC	
2 λ .06	+	+	Undiluted	-	-	+	+
λ .03	+	+	1:2	-	-	+	+
$\frac{1}{2}\lambda$.015	-	-	1:4	-	-	+	+
$\frac{1}{4}\lambda$.0075	-	-	1:8	-	-	+	+
NWC	-	-	1:16	-	-	+	+

NOTE: THESE RESULTS ARE NOT TO BE USED FOR END PRODUCT RELEASE.

Summary: The error for the Gel-Clot assay is +/- one two-fold dilution. The test article in this assay indicates an Endotoxin Concentration of < 0.03 EU/device.



signature
Study Director

07-02-2013

date



signature
Quality Reviewer

07-02-2013

date