

## CERTIFICATE OF QUALIFICATION

PRODUCT	celCradle-500 Bottle
PRODUCT NO.	1400001
LOT NO. / SERIAL NO.	Lot No.: 105030001 Serial No.: BC5-08514 ~ BC5-08593
DESCRIPTION	Disposable Device for Cell Culture
MANUFACTURE DATE	2016/08
EXPIRATION DATE	2018/07

Thank you for purchasing Esco Vaccixcell products. Our products pass the following inspection items:

QC item	Criteria	Result	Pass/Fail	Regulation
<i>Integrity Test</i>	No leakage	No leakage	Pass	N/A <sup>a</sup>
<i>Gamma Irradiation</i>	1. $\gamma$ -ray indicator turn red 2. $\gamma$ -ray dosage certificate	1. red 2. 18.2 kGy	Pass	N/A
<i>Durable Test</i>	No breakage	No breakage	Pass	N/A <sup>b</sup>
<i>LAL Test</i>	< 0.25 EU/ml	< 0.25 EU/ml	Pass	USP36-NF31 <85> <sup>c</sup>
<i>Biological Reactivity Test</i>	Grade 0	Grade 0	Pass	USP36-NF31 <87> <sup>d</sup>
<i>Bioburden Test</i>	$\leq 10$ CFU per bottle	0 CFU/bt	Pass	USP36-NF31 <61> <sup>e</sup>
<i>Average Amount of Carriers</i>	798 pcs $\leq$ 1 bottle $\leq$ 908 pcs	829 $\pm$ 7 pcs/bt	Pass	N/A <sup>a</sup>

Note :

a Pressure and Leakage Test @ 0.07 Kg/cm<sup>2</sup>, 100% inspection. Internal standards.

b 200,000 Compression-Expansion cycle Test.

c <85>BACTERIAL ENDOTOXINS TESTS, Gel Clot Method

d <87>BIOLOGICAL REACTIVITY TESTS *in Vitro*, L-929 Cell Culture Test (Serum-Containing Medium)

e <61>MICROBIAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS

I HEREBY CERTIFY THAT THIS ANALYSIS IS TRUE AND ACCURATE, AND EVERY PART AND MATERIAL WILL NOT BE ALTERED WITHOUT PRIOR WRITTEN NOTIFICATION OF IMPENDING MODIFICATIONS OF PRODUCT.



16 August 2016

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SIGNATURE OF QA ENGINEER

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DATE