



## CERTIFICATE OF ORIGIN

Clzyme AS

Version 19 Dec 2016

### COUNTRY OF ORIGIN

Clzyme AS, Catalog # 005-1090 is manufactured entirely within the United States by VitaCyte LLC.

### STATEMENT OF ANIMAL ORIGIN

None of the components used in the formulation of Clzyme AS use or come into contact with any ingredient of bovine origin during the manufacturing process. The only animal sourced material used in the manufacture of Clzyme AS is porcine gelatin peptone. This peptone is a culture media component used to stimulate collagenase biosynthesis from *Clostridium histolyticum*. Prior to inoculation with the organism, the culture media is sterilized for 30 minutes at 121°C, a process shown to inactivate many viruses.<sup>1</sup> Other biochemical contaminants in the culture supernatant are removed during the purification process.

### RISK OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

The use of porcine derived components represents a minimal risk of Transmissible Spongiform Encephalopathy (TSE). No evidence exists for naturally occurring TSE in pigs or transmission to pigs from infected tissue.<sup>2</sup>

#### Signatures:

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President

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Director of Quality Assurance

<sup>1</sup> International Federation for Animal Health Europe. Viral Inactivation Related to Steam Sterilisation of Biological Products. <http://www.ifaheurope.org/ifah-media/publications/215-viral-inactivation-1.html>; 2012 (Retrieved 19 Dec 2016)

<sup>2</sup> Wells, G.A.H.; et al. Portrait of experimental BSE in Pigs. In: Hornlimann, B.; Riesner, D.; Kretzschmar, H., eds. Prions in humans and animals. New York/Berlin: Walter de Gruyter; 2007: 275-278.