



## CERTIFICATE OF ORIGIN

DE Collagenase 400/40

Version 26 May 2019

### COUNTRY OF ORIGIN

DE Collagenase 400, Catalog #011-1030 and DE Collagenase 40, Catalog #011-1130 are manufactured entirely within the United States by VitaCyte LLC.

### STATEMENT OF ANIMAL ORIGIN

None of the components used in the formulation of DE Collagenase 400/40 use or come into contact with any ingredient of bovine origin during the manufacturing process. Porcine gelatin peptone is used during the fermentation of the *Clostridium histolyticum* organism to stimulate the collagenase biosynthesis. 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> No animal sourced materials are used during the collagenase purification process which largely removes culture media components. No animal sourced materials are used in the fermentation or purification of the BP Protease. The final product is formulated with a non-mammalian gelatin peptone based excipient.

### 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:

A handwritten signature in black ink, appearing to read 'Robert McCarthy'.

Robert McCarthy Ph.D.  
President

A handwritten signature in blue ink, appearing to read 'Andrew Breite'.

Andrew Breite M.S., M.B.A.  
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.