

### CERTIFICATE OF ORIGIN

# Clostripain

Version 4 Oct 2023

## COUNTRY OF ORIGIN

Clostripain, Catalog #004-1000 and #004-2000 are manufactured entirely within the United States by VitaCyte LLC.

# STATEMENT OF ANIMAL ORIGIN

None of the components used in the formulation of Clostripain 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 Clostripain is gelatin peptone derived from porcine skin. 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 inactive many viruses.<sup>1</sup> Other biochemical contaminants in the culture supernatant are removed during the purification process.

### RISK OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPAHTY

The use of porcine derived gelatin 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> Furthermore, no brain-heart infusion media is used at any stage of the Collagenase HA manufacturing process.

Signatures:

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President

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<sup>1</sup> International Federation for Animal Health Europe. Viral Inactivation Related to Steam Sterilisation of Biological Products. 2012

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<sup>&</sup>lt;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.