

CERTIFICATE OF ORIGIN

Collagenase NB 1 GMP Grade Cat. No.: N0002937 from Clostridium histolyticum; EC 3.4.24.3 lyophil.

Process of manufacture:	Fermentation
Sub-type/biosource:	Bacterial
Microbial species:	Clostridium histolyticum
Genetically modified organisms used in manufacturing process:	No
Does the fermentation process contain any animal components?	Yes
Animal tissue used in manufacturing process:	Bovine: Peptone (skin, bones, free from skull and vertebrate column)
Country of origin of the biological components:	Bovine peptone: United States of America Bovine milk (casein): New Zealand, Australia
Country of manufacture:	Germany
Animal(s) controlled by USDA (United States Department of Agriculture) or Foreign Government Facilities?	Yes
Are the animal(s) traceable back to the processing facility?	Yes
Is there any commingling with other animal materials?	No
Did animal(s) pass ante and post mortem testing?	Yes
Are allergenic materials used in the manufacturing process?	The product itself is allergenic

Comments:

The a. m. product does not contain and is not derived from specified risk material as defined in Commission Decision 97/534/EC and fulfills the requirements of the guideline of the European Pharmacopoeia Chapter 5.2.8 regarding TSE safety. On request, a letter of access which allows the use of the TSE-CEP for filing with the authorities and a TSE-risk Statement are issued by Nordmark.

Dr. A. Freter Quality Assurance Dr. C. Haering

Product Manager Collagenase NB