

Certification for Export to Korea: Medical Devices and Pharmaceuticals Containing Bovine Ingredients

This protocol is intended to only cover medical devices and pharmaceuticals for export to Korea that 1) contain bovine ingredients; 2) are completely processed/finished products; and 3) are regulated for entry into Korea by the Korean Food and Drug Administration (KFDA).

The bilaterally negotiated certification statements included in this protocol are not to be amended or revised (except as noted below for statement #3 where the actual bovine materials in the product must be listed). Statements must not be added or deleted without express permission from the Veterinary Services (VS) National Center for Import and Export (NCIE) Animal Products Exports Staff.

It is VS understanding that KFDA is NOT requiring this certificate for product registration purposes. For certification of shipments, exporters should follow general instructions provided on the Korea page of the International Animal Product Regulations. NOTE: Export certificates MUST be endorsed PRIOR to shipping. If the date on the shipping documents precedes the date of endorsement of the export certificate, Korea will refuse entry.

- The commodities covered under the protocol will be certified for export using the VS 16-4, Health Certificate-Export Certificate-Animal Products (see model certificate on next page).
- The certification statement regarding the US ruminant to ruminant feed ban must be a direct attestation by Veterinary Services (VS).
- All other certification statements are to be made on the basis of a notarized affidavit which must be provided by the manufacturer/exporter. Statements made on the basis of a notarized affidavit must be preceded by the notarized affidavit line as noted on the model certificate below.
- Statement number three must include the actual bovine materials used in the manufacture of the product. These should be listed in lieu of the examples provided (hide-derived collagen, pericardium). Identification and listing of the bovine materials must be specific to verify that they are not considered specified risk materials (SRMs).
- Although statement number three will be endorsed on the basis of a notarized affidavit, the manufacturer/exporter must provide supporting documentation to verify that the materials were derived only from animals that passed both ante and post mortem inspection under official veterinary supervision at approved slaughter facilities. [Slaughter facilities under FSIS supervision are approved.]
- The “product description box” should identify the type of product (medical device or pharmaceutical) and the bovine materials used in the manufacture of the product. These should be listed in lieu of the examples provided.
- Additional supporting documentation may be requested by the VS Area Office prior to endorsement of export certificates. VS Area Offices may also require a facility inspection if needed to verify information provided on the notarized affidavit.

**HEALTH CERTIFICATE
EXPORT CERTIFICATE
ANIMAL PRODUCTS**

PORT

DATE
AND NO.

This certificate is for Veterinary purposes only. It is valid for 30 days after the date of signature (in the case of transport by ship or rail, the time is prolonged by the time of the voyage).

This is to certify that rinderpest, foot-and-mouth disease, classical swine fever, swine vesicular disease, African swine fever, and contagious bovine pleuropneumonia do not exist in the United States of America.

ADDITIONAL DECLARATION

The United States prohibits the feeding of ruminants with ruminant origin meat-and-bone meal and greaves, and this prohibition is effectively enforced.

This office has on file a notarized affidavit from [company/mufacturer] verifying the accuracy of the statements below.

1. The certified products are U.S. origin and were manufactured at a facility approved by the competent authority.
2. The certified products were manufactured in accordance with U.S. laws and regulations intended to ensure that they are unlikely to transmit disease agents, including transmissible spongiform encephalopathies (TSEs).
3. The bovine materials used in the manufacture of the product [list – e.g., hide-derived collagen, pericardium] were derived from healthy cattle that received ante and post mortem inspection under official veterinary supervision at approved slaughter facilities.
4. The cattle from which the bovine materials were derived were not known to be related to any herd affected by bovine spongiform encephalopathy (BSE).
5. The bovine materials used in the manufacture of the products were not derived from nor contaminated with any specified risk materials: the skull, brain, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age or older; or the tonsils or distal ileum of cattle of all ages.
6. The certified products were manufactured using a rigorous process designed to effectively mitigate any risk of disease transmission and ensure their safety for their intended use.



(SIGNATURE OF ENDORSING OFFICIAL)

(TYPED NAME)

(TITLE OF ENDORSING OFFICIAL)

DESCRIPTION OF THE CONSIGNMENT

NAME AND ADDRESS OF EXPORTER

NAME AND ADDRESS OF CONSIGNEE

PRODUCT (quantity, unit of measure, and kind)

Medical devices containing [list bovine materials – e.g., hide-derived collagen, tendons, pericardium]

IDENTIFICATION

CONVEYANCE