CHAPTER 20

Model declaration

Declaration for the import from third countries and for the transit through ([2]) the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products

COUNTRY: UNITED STATES **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.			I.2. Certificate reference No			I.2.a.	
			I.3. Central competent authority				
			I.4. Local competent authority				
I.5. Consignee Name Address Postal code Tel.			I.6. Person responsible for the load in EU Name Address Postal code Tel.				
I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address				I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code			
I.13. Place of loading				I.14. Date of departure			
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references				I.16. Entry BIP in EU I.17.			
I.18. Description of commodity				I.19. Commodity code (HS code)			
				I.20. Quantity			
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐				I.22. Number of packages			
I.23. Seal/Container No				I.24. Type of packaging			

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COUNTRY: UNITED STATES

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

I.2. Certificate reference No	I.2.a.

I.25. Commodities certified for:

Technical use ☐

I.26. For transit through EU to third country ☐	I.27. For import or admission into EU ☑
Third country ISO code	

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments Manufacturing plant	Net weight	Batch number

COUNTRY: UNITED STATES

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

Part II: Certification

II. Health information	II.a. Certificate reference No	II.b.

DECLARATION

I, the undersigned, declare that the intermediate product referred to above is intended to be imported by me into or to be transited through the European Union and satisfies the definition of an intermediate product provided for in point 35 of Annex I to Commission Regulation (EU) No 142/2011[(1a)], and in particular that:

(1) it is intended for the manufacture of:

- [(2)]*either* [- medicinal products,]
- [(2)]*and/or* [- veterinary medicinal products,]
- [(2)]*and/or* [- medical devices for medical and veterinary purposes,]
- [(2)]*and/or* [- active implantable medical devices,]
- [(2)]*and/or* [- in vitro diagnostic medical devices for medical and veterinary purposes,]
- [(2)]*and/or* [- laboratory reagents,]
- [(2)]*and/or* [- cosmetic products;]

(2) its design, transformation and manufacturing stages have been sufficiently completed in order to qualify the material directly or as a component of a product intended for that purpose, except for the fact that it requires further manufacturing or transformation such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service as a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, an active implantable medical devices, an in vitro diagnostic medical device for medical and veterinary purposes or a cosmetic product in accordance with the European Union legislation[(1b)] applicable to those products or as a laboratory reagent;

(3) it has been derived from:

- [(2)]*either* [- material which may have originated from animals submitted to an illegal treatment as defined in Article 1(2)(d) of Council Directive 96/22/EC[(2a)] or in Article 2(b) of Council Directive 96/23/EC[(2b)];]
- [(2)]*and/or* [- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]
- [(2)]*and/or* [- carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:
  - (i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals;
  - (ii) heads of poultry;
  - (iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;
  - (iv) pig bristles;
  - (v) feathers;]
- [(2)]*and/or* [- blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]
- [(2)]*and/or* [- animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]
- [(2)]*and/or* [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]
- [(2)]*and/or* [- petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or

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Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

II.	**Health information**	II.a. Certificate reference No	II.b.

due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2)*and/or* [- blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2)*and/or* [- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2)*and/or* [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

(2)*and/or* [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;

(ii) the following originating from terrestrial animals:

- hatchery by-products,
- eggs,
- egg by-products, including egg shells;

(iii) day-old chicks killed for commercial reasons;]

(2)*and/or* [- animal by-products from aquatic or terrestrial invertebrates other than species pathogenic to humans or animals;]

(2)*and/or* [- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]

(2)*and/or* [- products derived from or generated by:

- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals,
- aquatic or terrestrial invertebrates other than species pathogenic to humans or animals,
- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]

(2)and/or [- animals and parts of animals, other than those referred to in Article 8 or Article 10 of Regulation (EC) No 1069/2009,

(i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;

(ii) foetuses;

(iii) oocytes, embryos and semen which are not destined for breeding purposes; and

(iv) dead-in-shell poultry;]

(2)*and/or* [- animal by-products other than Category 1 material or Category 3 material;]

(4) its outer packaging is labelled 'FOR MEDICINAL PRODUCTS / VETERINARY MEDICINAL PRODUCTS / MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES / ACTIVE IMPLANTABLE MEDICAL DEVICES / IN VITRO DIAGNOSTIC MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES / LABORATORY REAGENTS / COSMETIC PRODUCTS ONLY' and it is not intended to be diverted at any stage within the European Union for any other use;

(5) the consignment will be transported directly to the place of destination in the European Union as indicated under point I.12 of this declaration, that is:

(2)*either* [an establishment or plant for the production of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products, which has been registered in accordance with Article 23 of Regulation (EC) No 1069/2009],

(2)*or* [an establishment or plant which has been approved in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they may only be dispatched to an establishment or plant referred to in the preceding indent of this point.]

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Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

II.	**Health information**	II.a. Certificate reference No	II.b.

Notes

- Box reference I.19: use appropriate Harmonised System (HS) code in accordance with Commission Decision 2007/275/EC of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts in accordance with Council Directives 91/496/EEC and 97/78/EC (OJ L 116, 4.5.2007, p.9)
- Box reference I.25: technical use: any use other than for animal consumption.

(1a) OJ L 54, 26.2.2011, p. 1.

(1b) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1) and Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59), as appropriate.

(2) Delete as appropriate.

(2a) OJ L 125, 23.5.1996, p. 3.

(2b) OJ L 125, 23.5.1996, p. 10.

The importer

Name (in capital letters):
Address:

Date: Signature: