

**Declaration for the import 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 from non-EU countries**

GBHC144X v3.0 May 2022

<b>Part I. Details of dispatched consignment</b>							
<b>I.1 Consignor</b> Name: Address: Tel:		<b>I.2 Certificate reference no.</b>		<b>I.3 Central competent authority</b>			
		<b>I.2.a Not in use</b>		<b>I.4 Local competent authority</b>			
<b>I.5 Consignee</b> Name: Address: Tel:				<b>I.6 Person responsible for the load in Great Britain</b> Name: Address: Tel:			
<b>I.7 Country of origin</b>	<b>ISO code</b>	<b>I.8 Region of origin</b>	<b>Code</b>	<b>I.9 Country of destination</b>	<b>ISO code</b>	<b>I.10 Region of destination</b>	<b>Code</b>
<b>I.11 Place of origin</b> Name: Approval number: Address:  Name: Approval number: Address:  Name: Approval number: Address:				<b>I.12 Place of destination</b> <input type="checkbox"/> Custom warehouse Name: Approval number: Address:			
<b>I.13 Place of loading</b>				<b>I.14 Date of departure</b>			
<b>I.15 Means of transport</b> <input type="checkbox"/> Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other Identification: Documentation references:				<b>I.16 Entry BCP</b>			
				<b>I.17 Not in use</b>			

<b>II.a. Certificate reference no.</b>	<b>II.b.</b>
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<b>I.18 Description of commodity</b>			
<b>I.19 Commodity code (HS code)</b>	<b>I.21 Temperature of products</b> <input type="checkbox"/> Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen	<b>I.23 Seal / Container No.</b>	
<b>I.20 Quantity</b>	<b>I.22 Number of packages</b>	<b>I.24 Type of packaging</b>	
<b>I.25 Commodity certified for</b> <input type="checkbox"/> Technical use			
<b>I.26 <input type="checkbox"/> For transit through Great Britain to third country</b>		<b>I.27 <input type="checkbox"/> For import or admission into Great Britain</b>	
Third country	ISO Code		
<b>I.28 Identification of the commodities</b>			
Species (Scientific name)	Approval number of establishments / Manufacturing plant	Net weight	Batch number

## Part II. Certification

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

- (1) it is intended for the manufacture of:
- <sup>(2)</sup> *either* [- medicinal products,]
  - <sup>(2)</sup> *and/or* [- veterinary medicinal products,]
  - <sup>(2)</sup> *and/or* [- medical devices for medical and veterinary purposes,]
  - <sup>(2)</sup> *and/or* [- active implantable medical devices,]
  - <sup>(2)</sup> *and/or* [- in vitro diagnostic medical devices for medical and veterinary purposes,]
  - <sup>(2)</sup> *and/or* [- laboratory reagents,]
  - <sup>(2)</sup> *and/or* [- cosmetic products;]

II.a. Certificate reference no.	II.b.
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- (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 retained EU law <sup>(1)</sup> applicable to those products or as a laboratory reagent;
- (3) it has been derived from:
- <sup>(2)</sup>*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 or in Article 2(b) of Council Directive 96/23/EC;]
  - <sup>(2)</sup>*and/or* [- carcasses 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 retained EU law, but are not intended for human consumption for commercial reasons;]
  - <sup>(2)</sup>*and/or* [- carcasses 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 retained EU law:
    - (i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with retained EU law, 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;]
  - <sup>(2)</sup>*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 retained EU law;]
  - <sup>(2)</sup>*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;]
  - <sup>(2)</sup>*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;]
  - <sup>(2)</sup>*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 due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

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- <sup>(2)</sup>*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;]
- <sup>(2)</sup>*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;]
- <sup>(2)</sup>*and/or* [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]
- <sup>(2)</sup>*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;]
- <sup>(2)</sup>*and/or* [- animal by-products from aquatic or terrestrial invertebrates other than species pathogenic to humans or animals;]
- <sup>(2)</sup>*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;]
- <sup>(2)</sup>*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;]
- <sup>(2)</sup>*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;]

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<sup>(2)</sup>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 Great Britain for any other use;
- (5)** the consignment will be transported directly to the place of destination in Great Britain as indicated under point I.12 of this declaration, that is:
- <sup>(2)</sup>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],
- <sup>(2)</sup>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.]

## Notes

References to European Union legislation within this certificate are references to direct EU legislation which has been retained in Great Britain (retained EU law as defined in the European Union (Withdrawal) Act 2018) and can be viewed on the UK legislation website ([legislation.gov.uk](http://legislation.gov.uk)).

References to Great Britain in this certificate include Channel Islands and Isle of Man.

### Part I:

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 control posts in accordance with Council Directives 91/496/EEC and 97/78/EC.

Box reference I.25: Technical use: any use other than for animal consumption.

### Part II:

<sup>(1)</sup> 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, 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, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices, Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as appropriate.

<sup>(2)</sup> Delete as appropriate.

## The importer

Name (in capital letters):

Address:

Date:

Signature: