~~RME-00XXXX~~

MODEL ANIMAL HEALTH CERTIFICATE FOR THE ENTRY INTO THE UNION OF CONSIGNMENTS OF OOCYTES AND EMBRYOS OF BOVINE ANIMALS COLLECTED OR PRODUCED, PROCESSED AND STORED IN ACCORDANCE WITH REGULATION (EU) 2016/429 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AND COMMISSION DELEGATED REGULATION (EU) 2020/692 AFTER 20 APRIL 2021, DISPATCHED BY THE EMBRYO COLLECTION OR PRODUCTION TEAM BY WHICH THE OOCYTES OR EMBRYOS WERE COLLECTED OR PRODUCED (MODEL "BOV-OOCYTES-EMB-A-ENTRY")

COUNTRY: AUSTRALIA | **Animal health certificate [ETVD] to the EU**

Part I: Description of the consignment

I.1. Consignor/ Exporter
Name:
Address:
Country:
ISO country code:

~~I.2. Certificate reference~~
~~**RME-00XXXX**~~

~~I.2.a. IMSOC reference~~

I.3. Central Competent Authority
Department of Agriculture, Fisheries and Forestry

I.4. Local Competent Authority
Department of Agriculture, Fisheries and Forestry

~~QR CODE~~

I.5. Consignee/ Importer
Name:
Address:
Country:
ISO country code:

I.6. Operator responsible for the consignment
Name:
Address:
Country:
ISO country code:

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~~
AUSTRALIA	**AU**						

I.11. Place of dispatch
Name:
Address:
Country:
ISO country code:
Registration/Approval Number:

I.12. Place of destination
Name:
Address:
Country:
ISO country code:
Registration/Approval Number:

I.13. Place of loading **XXXXXXXXX, AUSTRALIA**

I.14. Date and time of departure: **DD/MM/YYYY**

I.15. Means of transport
☒Aeroplane ☐ Vessel
☐ Road vehicle ☐ Railway

Identification: Flights: **XXXXXX** MAWB: **XXXXXX**

I.16. Entry Border Control Post
XXXXXX

I.17.

I.18.	Transport conditions	□ Ambient	□ Chilled	☒ Frozen

I.19 Container number/Seal number
Container No: **XXXXXXXXXXX** Seal No: **XXXXXX**

I.20. Certified as or for ☒ Germinal products

~~I.21. For transit ☐~~
~~Third Country ISO code:~~

I.22. For internal market ☒

I.23.

I.24. Total number of packages
 # cryogenic tank

I.25. Total quantity
 # embryos

I.26.

I.27. Description of consignment

CN Code: **HS code 05 11 99 85** Species: **Bovine**

Subspecies/Category:	Identification number	Quantity	Type	Approval or registration number of plant/establishment centre	Identification mark	Date of collection/ production	Test
See attachment 1							

AUSTRALIA **Certificate model BOV-OOCYTES-EMB-A-ENTRY**

II. Health Information	~~II.a. Certificate reference No~~ **~~RME-00XXXX~~**	~~II.b. IMSOC reference No~~

Part II: Certification

I, the undersigned embryo transfer veterinarian, hereby declare that:

II.1. The [~~oocytes~~](1) [*in vivo* derived embryos](1) [~~*in vitro* produced embryos~~](1) [~~micromanipulated embryos~~](1) of the consignment described in Part I are intended for artificial reproduction and were obtained from donor animals which originate from a third country or territory, or zone thereof:

II.1.1. authorised for entry into the Union of [oocytes](1) [embryos](1) of bovine animals and listed in Annex IX to Commission Implementing Regulation (EU) 2021/404;

(1)*either* [II.1.2.where foot and mouth disease was not reported for a period of at least 24 months immediately prior to the date of [collection](1) [production](1) of the [oocytes](1) [embryos](1) and until the date of their dispatch;]

~~(1)*or* [II.1.2. where foot and mouth disease was not reported for a period starting on the date(2) ..... (*insert date dd/mm/yyyy*) immediately prior to the date of collection of the [oocytes](1)[embryos](1) and until the date of the dispatch;]~~

II.1.3. where infection with rinderpest virus, infection with Rift Valley fever virus, contagious bovine pleuropneumonia and lumpy skin disease were not reported for at least 12 months immediately prior to the date of [collection](1) [production](1) of the [oocytes](1) [embryos](1) and until the date of their dispatch;

II.1.4. where no vaccination against foot and mouth disease, infection with rinderpest virus, infection with Rift Valley fever virus and contagious bovine pleuropneumonia has been carried out for at least 12 months immediately prior to the date of [collection](1) [production](1) of the [oocytes](1) [embryos](1), and until the date of their dispatch, and no vaccinated animals entered into the third country or territory, or zone thereof during that period, and:

(1)*either* [no vaccination against foot and mouth disease has been carried out for the same period, and no vaccinated animals entered into the third country or territory, or zone thereof during that period.]

~~(1)or [vaccination against foot and mouth disease has been carried out for the same period, or vaccinated animals entered into the third country or territory, or zone thereof during that period.]~~

(1)[II.2. The [~~oocytes~~](1) [*in vivo* derived embryos](1) of the consignment described in Part I have been collected, processed and stored, and dispatched by the embryo collection team(3) which:

II.2.1. is approved and listed by the competent authority of the third country or territory;

II.2.2. complies with requirements as regards responsibilities, operational procedures, facilities and equipment set out in Part 2 of Annex I to Commission Delegated Regulation (EU) 2020/686.]

~~(1)[II.2. The [oocytes](1) [*in vitro* produced embryos](1) of the consignment described in Part I have been collected or produced, processed and stored, and dispatched by the embryo production team(3) which:~~

~~II.2.1. is approved and listed by the competent authority of the third country or territory;~~

~~II.2.2. complies with requirements as regards responsibilities, operational procedures, facilities and equipment set out in Parts 2 and 3 of Annex I to Delegated Regulation (EU) 2020/686.]~~

II.3. The [~~oocytes~~](1) [embryos](1) of the consignment described in Part I were obtained from the donor animals which originate from establishments:

II.3.1. free from infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), and they have never been kept previously in any establishment of a lower health status;

II.3.2. free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* and they have never been kept previously in any establishment of a lower health status;

(1)*either* [II.3.3. free from enzootic bovine leukosis and they have never been kept previously in any establishment of a lower health status;]

(1)*or* [II.3.3. not free from enzootic bovine leukosis and the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of enzootic bovine leukosis during at least the preceding 3 years prior to the date of [collection](1) [~~production~~](1) of the [~~oocytes~~](1) [embryos](1) and during the collection period;]

(1)*either* [II.3.4. free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis and they have never been kept previously in any establishment of a lower health status;]

(1)*or* [II.3.4. not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis and the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis during at least the preceding 12 months prior to the date of [collection](1) [~~production~~] of the [~~oocytes~~](1) [embryos](1) and during the collection period;]

II.3.5. in which:

(1)*either* [surra (*Trypanosoma evansi*) has not been reported during the last 2 years prior to the date of [collection](1) [~~production~~](1) of the [~~oocytes~~](1) [embryos](1)]

~~(1)*or* [surra (*Trypanosoma evansi*) has not been reported during the preceding 30 days prior to the date of [collection](1) [production](1) of the [oocytes](1) [embryos](1), and when the disease was reported in the establishments during the preceding 2 years prior to the date of [collection](1) [production](1) of the [oocytes](1) [embryos](1), following the date of the last outbreak the establishments have remined under movement restrictions until the date on which the infected animals have been removed from the~~

~~establishments, and the remaining animals in the establishments have been subjected to a test for surra with one of the diagnostic methods provided for in Part 3 of Annex I to Commission Delegated Regulation (EU) 2020/688, carried out, with negative results, on samples taken at least 6 months after the date on which the infected animals have been removed from the establishments.]~~

II.4. The [~~oocytes~~](1) [embryos](1) of the consignment described in Part I were obtained from the donor animals which:

II.4.1. were not vaccinated against infection with rinderpest virus, infection with Rift Valley fever virus, contagious bovine pleuropneumonia and lumpy skin disease;

II.4.2. remained for at least 6 months prior to the date of [collection](1) [~~production~~](1) of the [~~oocytes~~](1) [embryos](1) in a third country or territory, or zone thereof referred to in Box I.7.;

II.4.3. for at least 30 days prior to the date of [collection](1) [~~production~~](1) of the [~~oocytes~~](1) [embryos](1) and during the collection period:

II.4.3.1. were kept in establishments not situated in a restricted zone established due to the occurrence of foot and mouth disease, infection with rinderpest virus, infection with Rift Valley fever virus, contagious bovine pleuropneumonia or lumpy skin disease, or of an emerging disease relevant for bovine animals;

II.4.3.2. were kept in a single establishment where infection with *Brucella abortus*, *B. melitensis* and *B. suis*, infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), rabies, anthrax, surra (*Trypanosoma evansi*), enzootic bovine leukosis, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, bovine viral diarrhoea, infection with epizootic haemorrhagic disease virus and infection with bluetongue virus (serotypes 1-24) have not been reported;

II.4.3.3. were not in contact with animals from establishments situated in a restricted zone due to the occurrence of diseases referred to in point II.4.3.1. or from establishments which do not meet the conditions referred to in point II.4.3.2;

II.4.3.4. were not used for natural breeding;

II.4.4. were examined by the team veterinarian or a team member and did not show symptoms or clinical signs of transmissible animal diseases on the date of [collection](1) [~~production~~](1) of the [~~oocytes~~](1) [embryos](1);

II.4.5. are individually identified as provided for in Article 21(1) of Delegated Regulation (EU) 2020/692;

II.4.6. comply with the following conditions as regards foot and mouth disease:

II.4.6.1. they come from establishments:

- situated in an area where foot and mouth disease has not been reported within a 10-km radius centred on the establishment for at least 30 days immediately prior to the date of [collection](1) [~~production~~](1) of the [~~oocytes~~](1) [embryos](1);
- in which foot and mouth disease has not been reported during at least 3 months immediately prior to the date of [collection](1) [p~~roduction~~](1) of the [~~oocytes~~](1) [embryos](1);

(1)*either* [II.4.6.2. they were not vaccinated against foot and mouth disease;]

~~(1)(4)*or* [II.4.6.2. they were vaccinated against foot and mouth disease during the last 12 months prior to the date of collection of the embryos, and:~~

~~II.4.6.2.1. have not been vaccinated against foot and mouth disease within at least 30 days immediately prior to the date of collection of the embryos;~~

~~II.4.6.2.2. the semen used for fertilisation was collected from a male donor that complies with the conditions set out in Part 5, Chapter I, point 1(b) of Annex II to Delegated Regulation (EU) 2020/686 or the semen complies with the conditions set out in Part 5, Chapter I, point 2, of Annex II to Delegated Regulation (EU) 2020/686;~~

~~II.4.6.2.3. prior to freezing, the embryos have been subjected to trypsin washing carried out in accordance with the recommendations of the IETS Manual(5);~~

~~II.4.6.2.4. the embryos were stored deep frozen for at least 30 days from the date of collection, and during that period the donor animal has not shown clinical signs of foot and mouth disease;]~~

(1)(6)[II.4.7. comply with at least one of the following conditions as regards infection with bluetongue virus (serotypes 1-24):

~~(1)*either* [II.4.7.1. they have been kept for at least 60 days prior to the date of and during collection of the oocytes in a third country or territory, or zone thereof free from infection with bluetongue virus (serotypes 1-24) where no case of infection with bluetongue virus (serotypes 1-24) has been confirmed in the targeted animal population during the last 24 months;]~~

~~(1)(12)*and/or* [II.4.7.2. they have been kept in a seasonally disease-free zone, during the seasonally disease free period, for at least 60 days prior to and during collection of the oocytes;]~~

~~(1)*and/or* [II.4.7.3. they have been kept in a vector-protected establishment for at least 60 days prior to the date and during collection of the oocytes;]~~

(1)*and/or* [II.4.7.4. they have been subjected to a serological test able to detect specific antibodies against all serotypes (1-24), with negative results, between 28 and 60 days from the date of each collection of the oocytes;]

(1) *and/or* [II.4.7.5. they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on blood sample taken on the day of collection of the oocytes;]]

(1)(6)[II.4.8. comply with at least one of the following conditions as regards infection with epizootic haemorrhagic disease virus EHDV:

~~(1)~~ *either* [II.4.8.1. ~~they have been kept for at least 60 days prior to the date and during collection of the [oocytes](1) [embryos](1) in a third country or territory, or zone thereof where EHDV has not been reported for at least the preceding 2 years within a radius of 150 km of the establishments;]~~

~~(1)(13)~~ *and/or* [II.4.8.2. ~~they have been kept in a seasonally disease-free zone, during the seasonally disease-free period, for at least 60 days prior to the date of and during collection of the [oocytes](1) [embryos](1);]~~

~~(1)~~ *and/or* [II.4.8.3. ~~they have been kept in a vector-protected establishment for at least 60 days prior to the date of and during collection of the [oocytes](1) [embryos](1);]~~

(1) *and/or* [II.4.8.4. were resident in the third country or territory or zone thereof of dispatch of the [~~oocytes~~](1) [embryos](1) of the consignment to the Union in which according to official findings the following serotypes of EHDV exist: **1, 2, 5, 6, 7 & 8** and have been subjected with negative results in each case to the following tests carried out in an official laboratory:

(1) *either* [II.4.8.4.1. a serological test able to detect specific antibodies against those serotypes of EHDV, with negative results, on blood samples taken between 28 and 60 days from the date of the collection of the [~~oocytes~~](1) [embryos](1)]]

(1) *and/or* [II.4.8.4.2. an agent identification test for EHDV, with negative results, on blood samples taken on the day of collection of the [~~oocytes~~](1) embryos(1).]]]

~~(1)(6)[II.4.9. comply with animal health requirements laid down in Part 1, Chapter III, of Annex II to Delegated Regulation (EU) 2020/686;]~~

II.5. The [~~oocytes~~](1) [embryos](1) described in Part I:

II.5.1. have been collected, processed and stored in accordance with animal health requirements set out in [Part 2](1) [~~Part 3~~](1) [~~Part 4~~](1) [~~Part 5~~](1) and Part 6 of Annex III to Delegated Regulation (EU) 2020/686;

II.5.2. are placed in straws or other packages on which the mark is applied in accordance with requirements provided for in Article 83, point(a) of Delegated Regulation (EU) 2020/692 and that mark is indicated in box I.27;

II.5.3. are transported in a container which:

II.5.3.1. was sealed and numbered prior to the dispatch to the Union by the embryo collection or production team under responsibility of the team veterinarian, or by an official veterinarian, and the seal bears the number as indicated in Box I.19;

II.5.3.2. has been cleaned and either disinfected or sterilised before use, or is single-use container;

(1)(7)[II.5.3.3. has been filled in with the cryogenic agent which have not been previously used for other products;]

(1)(8)[II.5.4. are placed in straws or other packages which are securely and hermetically sealed;

II.5.5. are transported in a container where they are separated from each other by physical compartments or by being placed in secondary protective bags.]

(1)(9)[II.6. The [in vivo derived embryos](1) [~~in vitro produced embryos~~](1) [~~micromanipulated embryos~~](1) of the consignment described in Part I were conceived by artificial insemination using semen coming from a semen collection centre, germinal product processing establishment or germinal product storage centre approved for the collection, processing and storage of semen by the competent authority of a third country or territory, or zone thereof listed in Annex IX to Implementing Regulation (EU) 2021/404 for semen of bovine animals or by the competent authority of a Member State, and were collected, processed and stored in accordance with the requirements of Part 1, Chapter I and Part 5, Chapters II and III, of Annex II, and Part 1 of Annex III to Delegated Regulation (EU) 2020/686.]

(1)(10)[II.7. The following antibiotic or mixture of antibiotics(11) has been added to the collection, processing, washing or storage media: ……]

Notes

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, references to the Union in this animal health certificate include the United Kingdom in respect of Northern Ireland.

This animal health certificate shall be completed according to the notes for the completion of certificates provided for in Chapter 4 of Annex I to Commission Implementing Regulation (EU) 2020/2235.

Part I:

Box reference I.11: "*Place of dispatch*": Indicate the unique approval number and the name and address of the embryo collection or production team of dispatch of the consignment of oocytes or embryos. Only embryo collection or production teams listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the Commission website: http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm

Box reference I.12:	"*Place of destination*": Indicate the address and unique registration or approval number of the establishment of destination of the consignment of oocytes or embryos.
Box reference I.19:	Seal number shall be indicated.
Box reference I.24:	Total number of packages shall correspond to the number of containers.
Box reference I.27:	"*Species*": Select amongst "*Bos taurus*", "*Bison*" or "*Bubalus bubalis*" as appropriate. "*Type*": Specify if oocytes, in vivo derived embryos, in vitro produced embryos or micromanipulated embryos. "*Identification number*": Indicate the identification number of each donor animal. "*Identification mark*": Indicate the mark on the straw or other packages where oocytes or embryos of the consignment are placed. "*Date of collection/production*": Indicate the date on which oocytes or embryos of the consignment were collected or produced. "*Approval or registration number of plant/establishment/centre*": Indicate the unique approval number of the embryo collection or production team by which the oocytes or embryos were collected or produced. "*Quantity*": Indicate the number of straws or other packages with the same mark. "*Test*": Indicate for BTV-test: II.4.7.4. and/or II.4.7.5., and/or for EHD-test: II.4.8.3.1. and/or II.4.8.3.2., if relevant.'

Part II:

(1) Delete if not applicable.

(2) Only for a third country or territory, or zone thereof with an opening date in accordance with column 9 of the table in Part 1 of Annex II to Implementing Regulation (EU) 2021/404.'

(3) Only embryo collection or production teams listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the Commission website:

http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm.

(4) Option available only for the consignment of in vivo derived embryos.

(5) Manual of the International Embryo Transfer Society — A procedural guide and general information for the use of embryo transfer technology emphasising sanitary procedures, published by the International Embryo Transfer Society, 1 111 North Dunlap Avenue, Savoy, Illinois 61 874 USA

(http://www.iets.org/).

(6) Applicable for the consignment of oocytes and in vitro produced embryos.

(7) Applicable for frozen oocytes or embryos.

(8) Applicable for the consignment where in one container oocytes, in vivo derived embryos, in vitro produced embryos and micromanipulated embryos of bovine animals are placed and transported.

(9) Does not apply to oocytes.

(10) Mandatory attestation in case antibiotics were added.

(11) Insert the name(s) of the antibiotic(s) added and its(their) concentration

(12) For the zones with an entry "SF-BTV" in column 7 of the table in part 1 of Annex II to Implementing Regulation (EU) 2021/404.

(13) For the zones with an entry "SF-EHD" in column 7 of the table in part 1 of Annex II to Implementing Regulation (EU) 2021/404.

Embryo transfer veterinarian

Name (in capital letters):

Qualification and title:

Date:

Signature: ..... **(PDF only)**

Stamp

ATTACHMENT 1

I.27 Description of consignment					
CN Code: **HS code 05 11 99 85** Subspecies/ Category: **XXXXXX** Species: **Bovine** Approval or registration number of plant/establishment centre: **XXXXXX**					
Identification number	Quantity	Type	Identification mark	Date of collection/ production	Test